UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re INTUNIV ANTITRUST LITIGATION (Both Direct and Indirect Cases)	*	Civil Action Nos. 1:16-cv-12653-ADB 1:16-cv-12396-ADB

REVISED MEMORANDUM AND ORDER ON MOTIONS FOR SUMMARY JUDGMENT

BURROUGHS, D.J.

This "pay-for-delay" or "reverse settlement" case arises from an alleged anticompetitive agreement made between the brand and generic manufacturers of Intuniv, a medication used to treat Attention Deficit Hyperactivity Disorder ("ADHD"). Defendants Shire LLC and Shire U.S., Inc. (collectively, "Shire") manufacture Intuniv, which is the brand-name for extended release guanfacine hydrochloride. Defendants Actavis Elizabeth LLC, Actavis Holdco U.S., Inc., and Actavis LLC (collectively, "Actavis" and, together with Shire, "Defendants") manufacture a generic version of Intuniv. Plaintiffs, who include both Direct Purchaser Plaintiffs ("DPPs") and Indirect Purchaser Plaintiffs ("IPPs"), allege that they paid inflated prices for Intuniv due to Defendants' having improperly agreed to delay competition for both brand Intuniv and generic Intuniv in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C.

§§ 1–2. See generally [FWK 140].[1] The IPPs additionally bring state-law claims under the laws of Massachusetts, Florida, Missouri, New York, and Wisconsin, most of which are premised on alleged violations of the Sherman Act. [Picone 39 ¶¶ 155–508].

Presently before the Court are the parties' motions for summary judgment.[2] Plaintiffs have filed motions for summary judgment on Shire's market power, [FWK 294], and Defendants' readiness and ability to launch an authorized generic ("AG"), [FWK 295].[3] Defendants have moved for summary judgment on a number of issues: (1) Defendants did not agree that Shire would not launch an Intuniv AG; (2) there was no payment to delay generic competition; (3) Plaintiffs cannot recover based on a causal theory premised on launch at risk; (4) Plaintiffs cannot recover for purchases made before any anti-competitive agreement between Shire and Actavis; (5) Plaintiffs cannot establish market power; and (6) there is no evidence to support some of the IPPs' state-law claims. [FWK 327; Picone 244].

I. BACKGROUND

A. Factual Background

For the purposes of summary judgment, the following facts are undisputed. Defendants Shire LLC, a New Jersey corporation, and Shire U.S., Inc., a Kentucky corporation, are subsidiaries of Takeda Pharmaceutical Company Limited ("Takeda") and Shire PLC. [FWK

[1] For purposes of this memorandum and order, the Court refers to docket entries in FWK, et al. v. Shire, et al., 16-cv-12653 as "FWK [ECF No.]" and docket entries in Picone, et al. v. Shire, et al., 16-cv-12396 as "Picone [ECF No.]."

[2] On September 11, 2020, the Court granted the DPPs' motion for preliminary approval of its proposed settlement with Actavis. [FWK 493]. That settlement does not resolve the Plaintiffs' claims against Shire or the IPPs' claims against Actavis.

[3] The motions for summary judgment were filed by the DPPs but were subsequently joined by the IPPs. [Picone 237; Picone 238].

380-1 ¶ 7]. During the class period, Shire had its U.S. headquarters in Pennsylvania, which is where the employees who negotiated the underlying agreement worked at the time of the settlement. [FWK 380-1 ¶ 8]. Shire's headquarters is now in Massachusetts. [Id.].

Actavis Elizabeth LLC, Actavis Holdco U.S., Inc., and Actavis LLC are affiliates of Teva Pharmaceuticals Industries Limited and subsidiaries of Actavis, Inc. [FWK 380-1 ¶ 9]. The Actavis companies are incorporated in Delaware and have their principal places of business in New Jersey. [Id.].

On September 2, 2009, the Food and Drug Administration ("FDA") approved a New Drug Application ("NDA") for Shire's brand-name drug, Intuniv, a non-stimulant, once-daily, extended release formulation of guanfacine hydrochloride prescribed for pediatric and adolescent patients with ADHD. [FWK 380-1 ¶¶ 14–15; FWK 374-1 ¶ 2]. As a result, Intuniv received three years of regulatory exclusivity, during which time the FDA could not approve a generic version of Intuniv. [FWK 380 ¶ 15; FWK 374-1 ¶ 5]. Shire listed three patents in the FDA Orange Book as covering Intuniv: U.S. Patent Nos. 5,854,290 ("the '290 Patent"),[4] 6,287,599 ("the '599 Patent"),[5] and 6,811,794 ("the '794 Patent" and, collectively with the '290 Patent and the '599 Patent, "the Patents").[6] [FWK 380-1 ¶ 26; FWK 374-1 ¶ 3].

[4] Shire abandoned the '290 Patent in March 2012. [FWK 380-1 ¶ 27; FWK 374-1 ¶ 19]. Plaintiffs maintain that the patent was abandoned because it was revealed, during the underlying litigation, that the '290 Patent was invalidated by prior art. [FWK 380-1 ¶ 27; FWK 374-1 ¶ 19].

[5] The '599 Patent describes extended-release formulations that release the drug over time, rather than immediately. [FWK 280-1 ¶ 28]. It is set to expire on December 20, 2020, but has pediatric exclusivity until June 20, 2021. [Id.; FWK 374-1 ¶ 4].

[6] The '794 Patent claims a method of treating Attention Deficit Disorder and ADHD by administering a guanfacine or guanfacine H1 drug and reducing side effects that are often associated with guanfacine HC1. [FWK 280-1 ¶ 28]. It is set to expire on July 4, 2022, but has pediatric exclusivity until January 4, 2023. [Id.; FWK 374-1 ¶ 4].

A few months later, on December 29, 2009, Actavis filed an Abbreviated New Drug Application ("ANDA") for its proposed generic version of Intuniv. [FWK 380-1 ¶ 29; FWK 374-1 ¶ 7]. As part of that ANDA, Actavis argued that each patent listed in the Orange Book covering Intuniv was invalid or would not be infringed by Actavis' manufacture, use, or sale of generic Intuniv. [FWK 374-1 ¶ 8]. Several other companies subsequently sought FDA approval to manufacture their own generic alternatives to Intuniv. [FWK 380-1 ¶¶ 30–31, 34–35; FWK 374-1 ¶ 13]. As the first generic manufacturer to file an ANDA, Actavis would have enjoyed "a 180-day period of exclusivity" during which no other generic manufacturer could have manufactured an Intuniv alternative. In re Loestrin 24 Fe Antitrust Litig. (Loestrin I), 814 F.3d 538, 543 (1st Cir. 2016). During that exclusivity period, Shire and Actavis would have been the only manufacturers approved by the FDA to produce Intuniv or a generic alternative. [FWK 374-1 ¶ 9].

Actavis notified Shire of its ANDA on April 2, 2010. [FWK 374-1 ¶ 10]. On May 12, 2010, Shire filed suit, in the United States District Court for the District of Delaware, against Actavis pursuant to 21 U.S.C. § 335(j)(5)(B)(iii), [FWK 380-1 ¶ 33; FWK 374-1 ¶ 16], which triggered a 30-month stay of the FDA's approval of Actavis' ANDA for generic Intuniv, see Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. 136, 143 (2013) ("If the brand-name patentee brings an infringement suit within 45 days, the FDA then must withhold approving the generic, usually for a 30-month period, while the parties litigate patent validity (or infringement) in court." (citing 21 U.S.C. § 355(j)(5)(B)(iii))).

The Honorable Richard G. Andrews, United States District Judge for the District of Delaware, held a Markman hearing on the Patents on February 14, 2012. [FWK No. 380-1 ¶ 37]. The '599 Patent and '794 Patent each reference a formulation of guanfacine hydrochloride that

has three essential components: (1) an active pharmaceutical ingredient that is "pH dependent"; (2) a "non-PH dependent sustained release agent"; and (3) a "pH dependent agent" that increases the rate of release of the active ingredient at a pH greater than 5.5. [FWK 380-1 ¶ 37]. The court found that the active pharmaceutical ingredient referenced in component (1) must be a separate component from the non-pH dependent agent referenced in component (2). [Id.]. Therefore, Shire could not prove that Actavis had infringed on its patent through the presence of a single ingredient. [Id.]. Shire would have needed to prove that Actavis' allegedly infringing product contained at least one ingredient that was a non-pH dependent sustained release agent and a different ingredient that functioned as the pH-dependent agent. [Id.]. Shire moved for reconsideration, which the court denied. [Id.].

The court denied Actavis' motion for summary judgment on September 6, 2012, [FWK No. 380-1 ¶ 38], and held a bench trial from September 17 to September 20, 2012 on Shire's infringement claims on the '599 Patent and the '794 Patent, [FWK 380-1 ¶ 39; FWK 374-1 ¶ 23].

Prior to this trial, on June 29, 2012, the FDA tentatively approved Actavis' ANDA. [FWK 380-1 ¶ 47; FWK 374-1 ¶ 20]. On August 7, 2012, Jennifer Wu, the Actavis project manager in charge of meeting Actavis' generic Intuniv launch deadlines, reported that Actavis had sufficient raw materials to manufacture launch quantities of generic Intuniv. [FWK 374-1 ¶ 36; FWK 380-1 ¶ 48]. Over the next few months, from August until October 2012, Actavis manufactured twelve process validation batches of generic Intuniv. [FWK 374-1 ¶¶ 37–38]. Wu notified the generic Intuniv team that the process validation batches were "launch ready" on October 19, 2012. [FWK 374-1 ¶ 39].

On October 5, 2012, the FDA gave final approval to Actavis' ANDA. [FWK 380-1 ¶ 47; FWK 374-1 ¶ 24].

Around this same time, Shire was also preparing test batches of generic Intuniv, one lot of each strength, in preparation for launching its own AG. [FWK 374-1 ¶¶ 59–61]. Those lots of generic Intuniv were delivered to Shire's distribution warehouse by November 20, 2012. [FWK 374-1 ¶¶ 62–63].

Throughout the underlying patent litigation, Shire and Actavis engaged in settlement negotiations. On April 19, 2012, Shire's in-house patent counsel sent Actavis' Director of IP Law a proposed settlement. [FWK 380-1 ¶ 49]. Shire's proposal included a January 2019 license effective date for Actavis' generic Intuniv, provided Shire with a 60% royalty, which would decline to 15% as more generic alternatives entered the market,[7] and reserved Shire's right to launch an AG, either itself or by using a third party. [Id.].

On September 21, 2012, after the bench trial before Judge Andrews, Actavis sent a counter-proposal to Shire. [FWK 380-1 ¶ 50]. Actavis' proposed settlement provided that Shire would grant Actavis a royalty-free license effective October 2013 and that Shire would not launch an AG. [Id.]. Shire responded on November 2, 2012, by sending a proposal to Actavis' Vice President and Intellectual Property and Patent Counsel, which included a January 1, 2016 license effective date, a 15% royalty to Shire when Shire was in the market with another generic or an AG, which would decline to 5% as more generics entered the market, and a provision indicating that Shire would retain the right to launch an AG, either itself or through an affiliate, but would not launch that AG using a third party during the first 180 days of Actavis' generic

[7] Specifically, the proposal provided that Shire's 60% royalty would decline to 25%, if Actavis was on the market with one other generic or AG, and to 15% if there was more than one other generic alternative. [FWK 380-1 ¶ 49].

entering the market. [Id. ¶ 51]. Between November 20, 2012 and January 7, 2013, Defendants' respective General Counsels had six telephone calls to discuss settlement. [Id. ¶ 53].

On January 16, 2013, Actavis' General Counsel sent Shire's General Counsel a mark-up of Shire's November 2, 2012 settlement offer. The mark-up proposed a September 2014 launch date for Actavis' generic, an unspecified royalty that would terminate upon another generic or AG entering the market, and forfeited Shire's right to launch an AG, either itself or through a third party. [FWK 380-1 ¶ 60]. Shire's General Counsel responded on February 5, 2013 with a proposal that left the September 2014 launch date and, accepted that Shire's royalty, which remained unspecified, would terminate upon another generic entering the market, but reserved Shire's right to launch an AG during Actavis' 180-day period of market exclusivity. [Id. ¶ 61].

On February 27, 2013, Shire's General Counsel and CEO met in New York with Actavis' General Counsel and CEO, and reached an "outline agreement," in which they agreed to a December 1, 2014 launch date and an average 25% royalty to Shire, the exact percentage of which was left open for further discussion and would depend on the number of generics in the market. [FWK 380-1 ¶ 62]. They did not, however, reach an agreement as to Shire's ability to launch an AG during Actavis' 180-day period of market exclusivity. [Id.]. According to Plaintiffs, the 25% royalty was conditioned upon Actavis being the only generic Intuniv product on the market, meaning that Shire was agreeing not to launch an AG. [Id.].

On March 4, 2013, Actavis' General Counsel sent Shire's General Counsel another round of proposed changes to the settlement agreement. [FWK 380-1 ¶ 63]. The proposal incorporated the agreed-upon December 1, 2014 launch date, but included a declining royalty rate. [Id.]. Specifically, Shire would receive a 30% royalty during the first 60 days of Actavis' generic entering the market, a 25% royalty during the second 60 days, and a 20% royalty during the final

60 days. [Id.]. The royalty would terminate completely if another generic alternative entered the market, including a Shire AG. [Id.]. On March 7, 2013, Shire sent Actavis its markup of the proposed settlement agreement. [FWK 380-1 ¶ 64]. Shire's response maintained the December 1, 2014 entry date and the declining royalty structure, but also retained Shire's right to launch an AG, either itself or through an affiliate, during Actavis' 180-day period of market exclusivity. [Id.].

On March 22, 2013, Shire's General Counsel sent Actavis' General Counsel a draft provision concerning Shire's ability to launch an AG which provided that, if such an agreement were "permitted by law," then Shire would agree not to launch an AG, either itself or through a third party.[8] [FWK 380-1 ¶ 67].

On March 31, 2013, Actavis' General Counsel sent Shire's General Counsel a markup of Shire's March 7, 2013 proposal, which retained the December 1, 2014 effective date and the 180-day royalty period. [FWK 380-1 ¶ 69]. The proposal, however, modified Shire's ability to

[8] That provision provided:

> [T]he License and Authorization shall become exclusive on the effective date of the Amendment with respect to AG Product, even as to Shire . . . if Shire's grant of such exclusive license contemplated by this Section becomes Permitted by Law in the Territory.
>
> As used in this section, the term "Permitted by Law" shall mean federal Law as interpreted by the U.S. Supreme Court or enacted by Congress and which federal Law preempts application of any state or local Law to Shire's grant of the exclusive license contemplated by this Section.
>
> For avoidance of any doubt, as of the Effective Date and unless amended as contemplated by this Section, the License and Authorization is non-exclusive as to Shire's right itself or through an Affiliate to Market an AG Product as provided in Section 2.3

[FWK 380-1 ¶ 67].

launch an AG, required that Shire give 90 days' notice if it was going to launch an AG, and provided that Shire's royalty would be terminated if it launched an AG during Actavis' 180-day period of market exclusivity. [Id.]. In addition to losing its royalty, Shire would need to refund Actavis for any previously paid royalties if Shire entered the generic market with an AG. [Id.]. Shire's General Counsel responded on April 4, 2013 and proposed that Shire retain its right to launch an AG, either itself or through an affiliate, but that it would give 90 days' notice if it was going to launch through a third party. [Id. ¶ 70]. Additionally, Shire removed the provision that would have required that it refund previously paid royalties if it entered the generic market with an AG. [Id.]. Thereafter, the parties continued to discuss the settlement over the phone. [Id. ¶¶ 71–72].

On April 12, 2013, Shire's General Counsel sent Actavis' General Counsel another markup of the March 31, 2013 proposal. [FWK 380-1 ¶ 73]. This markup included the December 1, 2014 launch date, a 25% royalty which would terminate if another generic product entered the market, including an AG, but without any refunds of previous royalties. [Id.]. Additionally, Shire deleted the "Permitted by Law" provision and added that it would provide 90 days' notice only if Shire launched an AG, either itself or through a third party, before the December 1, 2014 launch date. [Id.]. Actavis' General Counsel responded on April 14, 2013, with a proposal that reinserted the provision that Shire would provide notice of an AG launch at any point during the 180-day period of exclusivity. [Id. ¶ 74]. If Shire failed to provide such notice, then it would be prohibited from launching an AG. [Id.]. Shire rejected the notice provision. [Id. ¶ 75].

On April 25, 2013, before the Delaware district court issued its opinion, Shire and Actavis executed the final Settlement Agreement and attached License Agreement (collectively

"the Agreement"). [FWK 380-1 ¶ 78; FWK 374-1 ¶¶ 66–67]. The Agreement provided that Actavis could make and market generic Intuniv effective December 1, 2014. [FWK 380-1 ¶ 81; FWK 374-1 ¶ 68]. Shire would receive a 25% royalty during Actavis' first 180 days on the market, so long as Actavis was the only generic Intuniv product on the market.[9] [FWK 380-1 ¶ 81 § 5.1; FWK 374-1 ¶ 69]. Shire could "not authorize or license a Third Party to market or sell AG Product at any time" before the end of Actavis' 180 days of exclusivity or another generic entering the market. [FWK 380-1 ¶ 81 § 2.3]. "Shire explicitly retain[ed] the right itself, or through an Affiliate, to Market at any time an AG Product." [Id.]. Additionally, Shire retained its right to grant a license to its patents to a third party to market or sell a generic product and could supply an AG to a third party to market either after Actavis' 180-day period of market exclusivity or after other generic products entered the market, but, in the event of a third party launch or a Shire launch before Actavis' launch date, would provide Actavis with 90 days' notice. [Id.]. Additionally, if Shire launched an AG without providing 90 days' notice, then Actavis was entitled to specific enforcement, including an immediate injunction. [Id. ¶ 81 § 8.8.2].

Plaintiffs argue that it appeared likely that the Delaware district court's verdict in the underlying patent dispute was going to be in Actavis' favor and that the settlement was a reverse payment agreement, which guaranteed Actavis a 180-day exclusivity period in return for its delaying the launch of generic Intuniv until December 1, 2014. [FWK 380-1 ¶ 41].

[9] Regarding termination of royalties, the Agreement specifies that "[f]or the avoidance of doubt, this royalty obligation is terminated on the date of the First Commercial Sale by a Third Party or Shire or its Affiliates of a Generic Equivalent Product or an AG Product in the Territory, so that [Actavis] will owe no royalty on [Actavis] Generic Products sold by [Actavis] after such date." [FWK 380-1 ¶ 81 § 5.1].

Tina Picone is a resident of New York and a legal guardian for a minor for whom she purchased brand and generic Intuniv. [FWK 380-1 ¶ 3]. Carmen Richard lived in Massachusetts until May 2012, at which point she moved to New Hampshire. [Id. ¶ 4]. She purchased brand Intuniv once in Massachusetts in March 2013 and paid a co-pay. [Id.]. She then only purchased generic Intuniv in Florida. [Id.]. Shana Wright is a Missouri resident who was the legal guardian of two minors for whom she purchased Intuniv. [Id. ¶ 5]. Finally, Sherry Cummisford is a resident of Wisconsin and legal guardian of a minor for whom she purchased Intuniv. [Id. ¶ 6].

B. Procedural History: the DPP Case

FWK Holdings, LLC ("FWK") filed its complaint on December 30, 2016, asserting two causes of action under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1–2. [FWK 1]. Rochester Drug Co-Operative, Inc. ("RDC") filed similar claims on January 11, 2017, and the Court granted a joint motion to consolidate the two actions. [FWK 19].

On September 24, 2019, the Court granted the DPPs' motion to certify the following class:

> All persons or entities in the United States and its territories, or subsets thereof, that purchased Intuniv and/or generic Intuniv in any form directly from Shire or Actavis, including any predecessor or successor of Shire or Actavis, from October 19, 2012 through June 1, 2015 (the "Class").

[FWK 343 at 4, 23]. The Court, however, dismissed FWK as a class representative after finding that the relationship between FWK and class counsel was too entangled. [Id. at 16]. Though the Court had reservations about RDC's adequacy as a class representative, it ultimately agreed that RDC could serve as class representative. [Id. at 17–18].

On March 12, 2020, RDC filed for Chapter 11 bankruptcy in the United States Bankruptcy Court for the Western District of New York. See In re Rochester Drug

Co-Operative, Inc., No. 20-cv-20230 (Bankr. W.D.N.Y.). In light of RDC's bankruptcy, Defendants moved to decertify the DPP class. [FWK 404]. The Court granted the motion in part and found that RDC could no longer adequately represent the interests of absent class members due to a conflict of interest arising from its bankruptcy. [FWK 456]. The Court declined to decertify the class, however, and allowed motions to intervene. [Id. at 14–15]. On July 24, 2020, the Court granted a motion to intervene from Meijer, Inc. and Meijer Distribution, Inc. (collectively "Meijer"), a pharmacy retailer headquartered in Michigan and member of the DPP class. [FWK 462]. The parties were granted thirty days of discovery concerning Meijer's adequacy before Meijer could move to be appointed class representative. [Id. at 20].

C. Procedural History: The IPP Case

Picone filed a class action complaint on October 31, 2016. [Picone 1]. On March 10, 2017, Picone then filed, with Cummisford, Richard, and Wright, a consolidated and amended class action complaint . [Picone 39]. The IPPs bring fifteen causes of action against Defendants under Massachusetts General Laws chapter 93A, New York General Business Law §§ 340 *et seq.*, Florida's Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201 *et seq.* and the Florida Antitrust Act, Fla. Stat. §§ 542.15 *et seq.*, the Wisconsin Antitrust Act, Wis. Stat. §§ 133.03 *et seq.*, and the Missouri Merchandising Practices Act, Mo. Rev. Stat. §§ 407.10 *et seq.* and Missouri Antitrust Act, Mo. Rev. Stat. §§ 416.011 *et seq.* [Picone 39]. The IPPs bring ten additional causes of action against Shire alone under those same state laws. [Id.].

On August 21, 2019, the Court denied the IPPs' motion to certify two classes of indirect purchasers. [Picone 230]. The IPPs filed a petition with the First Circuit to appeal the Court's decision. The IPPs also filed a motion with this Court, requesting that the Court reconsider its denial of class certification. [Picone 235]. Because the motion for reconsideration asked the

Court to consider the same issues that were pending before the First Circuit in the interlocutory appeal, and because the Court found that the motion for reconsideration lacked merit, the Court denied the motion. [Picone 276]. The IPPs then filed a motion for leave to file a motion to request that the Court alter its order denying class certification, [Picone 294], which the Court denied, [Picone 325]. On September 10, 2020, the First Circuit denied the IPPs' petition to appeal the Court's decision regarding class certification. [Picone 336].

II. LEGAL STANDARD

Summary judgment is appropriate where the movant can show that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A fact is material if its resolution might affect the outcome of the case under the controlling law. . . . A genuine issue exists as to such a fact if there is evidence from which a reasonable trier could decide the fact either way." Cochran v. Quest Software, Inc., 328 F.3d 1, 6 (1st Cir. 2003) (citation omitted).

"To succeed in showing that there is no genuine dispute of material fact," the moving party must point to "specific evidence in the record that would be admissible at trial." Ocasio-Hernández v. Fortuño-Burset, 777 F.3d 1, 4 (1st Cir. 2015). "That is, it must 'affirmatively produce evidence that negates an essential element of the non-moving party's claim,' or, using 'evidentiary materials already on file . . . demonstrate that the non-moving party will be unable to carry its burden of persuasion at trial.'" Id. at 4–5 (quoting Carmona v. Toledo, 215 F.3d 124, 132 (1st Cir. 2000)). "One of the principal purposes of the summary judgment rule is to isolate and dispose of factually unsupported claims or defenses . . . ." Celotex Corp. v. Catrett, 477 U.S. 317, 323–24 (1986). Once the movant takes the position that the record fails to make out any trial-worthy question of material fact, "it is the burden of the nonmoving party

to proffer facts sufficient to rebut the movant's assertions." Nansamba v. N. Shore Med. Ctr., Inc., 727 F.3d 33, 40 (1st Cir. 2013).

In reviewing the record, the Court "must take the evidence in the light most flattering to the party opposing summary judgment, indulging all reasonable inferences in that party's favor." Cochran, 328 F.3d at 6. The First Circuit has noted that this standard "is favorable to the nonmoving party, but it does not give him a free pass to trial." Hannon v. Beard, 645 F.3d 45, 48 (1st Cir. 2011). "The factual conflicts upon which he relies must be both genuine and material," Gomez v. Stop & Shop Supermarket Co., 670 F.3d 395, 397 (1st Cir. 2012), and the court may discount "conclusory allegations, improbable inferences, and unsupported speculation," Cochran, 328 F.3d at 6 (quoting Medina-Munoz v. R.J. Reynolds Tobacco Co., 896 F.2d 5, 8 (1st Cir. 1990)). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." Medina-Munoz, 896 F.2d at 8 (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249–50 (1986)).

III. REGULATORY FRAMEWORK

Brand-name manufacturers, such as Shire, that seek to market a new brand-name drug, such as Intuniv, must file an NDA, which includes a "long, comprehensive, and costly testing process." Actavis, 570 U.S. at 142. The brand manufacturer is required to "list the numbers and expiration dates of all relevant patents in their NDAs, which are then published in the FDA's 'Orange Book,' an annual publication of all approved drugs and the reported patents or statutory exclusivities that cover those drugs." In re Nexium (Esomeprazole) Antitrust Litig. (Nexium I), 842 F.3d 34, 40 (1st Cir. 2016).

Generic manufacturers, like Actavis, however, can use an accelerated approval process by filing an ANDA. Through the ANDA, the generic company "specif[ies] that the generic has

the 'same active ingredient as,' and is 'biologically equivalent' to, the already-approved brand-name drug." Actavis, 570 U.S. at 142 (quoting Caraco Pharma. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 405 (2012)). The generic must also "'assure the FDA' that the generic 'will not infringe' the brand-name's patents." Id. at 143 (quoting Caraco, 566 U.S. at 406). The generic company may do this in one of four ways: (1) by certifying that the brand manufacturer has failed to list any relevant patents in the Orange Book; (2) by certifying that the relevant patents have expired; (3) by requesting the FDA's approval to market its generic upon the expiration of any patents that are still active; or (4) by certifying that "any listed, relevant patent 'is invalid or will not be infringed by the manufacture, use, or sale'" of the generic drug. Nexium I, 842 F.3d at 40 (quoting Actavis, 570 U.S. at 144). Relevant to this case is the generic company's fourth option, often called a "paragraph IV certification." Id.

The generic company who first files a properly-certified ANDA obtains the benefit of a 180-day period of market exclusivity, during which time the FDA cannot approve ANDAs from other generic manufacturers seeking to manufacture generic versions of the brand drug at issue. Actavis, 570 U.S. at 143–44. That period of market exclusivity "can be 'worth several hundred million dollars'" and usually constitutes the "'vast majority of potential profits for a generic drug manufacturer.'" Nexium I, 842 F.3d at 41 (quoting Actavis, 570 U.S. at 144). During that 180-day period of market exclusivity, the generic company will likely face competition only from the brand company and an AG from the brand company.

> An AG is a generic version of a drug, authorized by a branded drug maker under its own FDA approval. The branded firm may market the drug itself or, more commonly, contract with a generic drug maker to do so. AGs have been an important feature of generic product launches since the 2000s. Courts have consistently held that an AG may be marketed even during the 180-day exclusivity period of an independent generic drug maker provided for in certain circumstances under the Hatch-Waxman Act.

Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, The *Actavis* Inference: Theory and Practice, 67 Rutgers U. L. Rev. 585, 595 (2015).

A paragraph IV certification "usually triggers an immediate patent infringement suit from the brand-name manufacturer," Nexium I, 842 F.3d at 40, as it did in this case. When a brand manufacturer brings such an infringement claim, the FDA must withhold its approval of the generic company's ANDA for thirty months. Id. If the court considering the patent infringement case reaches a decision on infringement, then the FDA follows that court's determination. Id. If, however, the thirty-month period expires before the court reaches a decision on infringement, as happened in this case, then the FDA may approve the ANDA, despite the potential patent infringement. Id.

Such approval with the potential for an infringement claim presents the generic company with the dilemma of whether it should launch "at risk," that is, "with the risk of losing the infringement case against it hanging over its head." Nexium I, 842 F.3d at 40–41 (quoting In re Nexium (Esomeprazole) Antitrust Litig. (Nexium II), 42 F. Supp. 3d 231, 245 (D. Mass. 2014)). "Losing an infringement case after launching at risk can result in significant liability for the generic manufacturer, as damages typically are calibrated by the amount of its at-risk sales." Id.

IV. DISCUSSION

A. Market Power

Both parties seek summary judgment on the issue of whether Plaintiffs have established that Shire had market power. See [FWK 294; FWK 312 at 51]. Plaintiffs argue that a reasonable jury could only conclude that Intuniv was so unlike other ADHD treatments that it created a market unto itself, in which Shire had a complete monopoly. [FWK 303 at 5–6]. Defendants argue that no reasonable factfinder could find that Plaintiffs have met their burden of proof in establishing that Shire had market power. [FWK 312 at 50]. Defendants further assert that the

relevant market is all non-stimulant ADHD treatments, a market in which Shire had only a 30% share. [FWK 358-1 at 5].[10]

"[A] reverse payment typically arises where a brand-name drug manufacturer pays the generic manufacturer to delay entry of its generic equivalent, thereby protecting the brand's market from generic competition." Loestrin I, 814 F.3d at 542. "Market power is the ability to raise price profitably by *restricting output*." Ohio v. Am. Express Co., 138 S. Ct. 2274, 2288 (2018) (quoting P. Areeda & H. Hovenkamp, Fundamentals of Antitrust Law § 5.01 (4th ed. 2017)).

Under Section 1 of the Sherman Act, Plaintiffs must show that Shire exercised or could have exercised its market power to lessen or eliminate competition in the relevant market. Flovac, Inc. v. Airvac, Inc., 817 F.3d 849, 853 (1st Cir. 2016). Similarly, under Section 2, "Plaintiffs may demonstrate monopoly power the same way they demonstrate market power, although a showing of monopoly power for the purposes of Section 2 is held to a higher standard than for Section 1." In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14-md-02503, 2018 WL 563144, at *4 n.5 (D. Mass. Jan. 25, 2018) (internal citations omitted). Plaintiffs must "show that [D]efendants' actions enhanced market power—i.e. the power to raise prices or exclude competition—which in turn requires some economic analysis of the relevant market." Am. Steel Erectors, Inc. v. Local Union No. 7, Int'l Ass'n of Bridge, Structural, Ornamental & Reinforcing Iron Workers, 815 F.3d 43, 61 (1st Cir. 2016) (internal quotation marks omitted). Thus, Plaintiffs must show that Defendants "exercise[d] or could

[10] The market of non-stimulant ADHD treatments would also include branded Strattera (atomoxetine); branded and generic Kapvay (clonidine extended release); generic Tenex (guanfacine immediate release); branded and generic Catapres (clonidine immediate release); and generic Intuniv (guanfacine extended release). [FWK 380-1 ¶ 17].

[have] exercise[d] a threshold degree of market power" in order "to lessen or eliminate competition in the relevant market." Flovac, Inc., 817 F.3d at 853. "The definition of the market at issue is a question of fact." In re Loestrin 24 Fe Antitrust Litig. (Loestrin II), 433 F. Supp. 3d 274, 301 (D.R.I. 2019); see also Flovac, 817 F.3d at 853 ("The definition of the relevant market is ordinarily a question of fact . . . .").

"To determine whether products are in the same market, [the Court considers] 'if they are readily substitutable for one another,' an inquiry that requires [the Court] to assess 'the reasonable interchangeability of use between a product and its substitute.'" Fed. Trade Comm'n v. AbbVie Inc., 329 F. Supp. 3d 98, 128 (E.D. Pa. 2018) (quoting Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd., 838 F.3d 421, 435 (3d Cir. 1994)). Market power may be established through direct evidence or indirect evidence. See Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Corp., 79 F.3d 182, 196–97 (1st Cir. 1996) ("Market power can be shown through two types of proof. A plaintiff can either show direct evidence of market power (perhaps by showing actual supracompetitive prices and restricted output) or circumstantial evidence of market power." (citing Rebel Oil Co. v. Alt. Richfield Co., 51 F.3d 1421, 1434 (9th Cir. 1995))).

The Supreme Court has explained that its "prior cases support the proposition that in some instances one brand of a product can constitute a separate market." Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 482 (1992); see, e.g., In re Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279, 1319 n.40 (S.D. Fla. 2005) (defining the relevant market as a branded drug and its generic options); In re Cardizem CD Antitrust Litig., 105 F. Supp. 2d 618, 680–81 (E.D. Mich. 2000) (finding on a motion to dismiss that the relevant market could be a branded drug and its generic counterpart), aff'd, 332 F.3d 896 (6th Cir. 2003); In re Nexium (Esomeprazole) Antitrust Litig. (Nexium III), 968 F. Supp. 2d 367, 388 (D. Mass. 2013) (finding

that the relevant market could be restricted to a brand drug and its generic counterpart for purposes of surviving a motion to dismiss).

1. Direct Evidence of Market Power

Direct evidence of market power includes evidence of "actual supracompetitive prices and restricted output." Coastal Fuels, 79 F.3d at 196; see Eric Cramer and Daniel Berger, The Superiority of Direct Proof of Monopoly Power and Anticompetitive Effects in Antitrust Cases Involving Delayed Entry of Generic Drugs, 39 Univ. S.F.L. Rev. 81, 84 (2004) ("[F]or instance, evidence showing that cessation of the alleged anticompetitive conduct (i.e., allowing generic competitors to enter the market) led directly to substantially lower prices or increased output (or both) would be *direct* proof that the conduct (1) had anticompetitive effects pursuant to Section 1 and (2) constituted the exercise of monopoly power under Section 2."). If the Plaintiffs have actual direct evidence of market power, they need not establish the relevant market. Díaz Aviation Corp, v. Airport Aviation Servs., Inc., 716 F.3d 256, 265 (1st Cir. 2013) ("Absent direct proof of supracompetitive prices, monopoly power is typically proven by defining a relevant market and showing that the defendant has a dominant share of that market."); see also Nexium III, 968 F. Supp. 2d at 388 n.19 ("Where direct evidence of market power is available . . . a plaintiff need not attempt to define the relevant market.").

Plaintiffs argue that there are three types of direct evidence that sufficiently support their motion for summary judgment: Shire's supracompetitive prices and gross margins; Shire's restricted output; and Shire's large and unexplained reverse payment to Actavis to delay entry of Actavis' generic. [FWK 303 at 7].

a. Shire's Supracompetitive Prices and Gross Profit Margins

Plaintiffs' expert, Dr. Martha Starr, asserts that Shire's gross profit margins on Intuniv were between 90% and 97%. [FWK 312 at 53; FWK 301-1 ¶ 62]. The Lerner Index "is a ratio

of a product's margin, or the difference between the price and marginal cost, to its price. The ratio falls between 0 and 1, 0 indicating the complete absence of market power and 1 representing complete market power . . . ." Solodyn, 2018 WL 563144, at *10. Dr. Starr found that Shire's ratio on the Lerner Index fell between .90 and .97. [FWK 374-1 ¶ 90].

"[W]hen direct evidence is available that a party profitably charges supracompetitive prices, the existence of market power can be established from that fact alone . . . ." In re Aggrenox Antitrust Litig., 94 F. Supp. 3d 224, 246 (D. Conn. 2015). Courts have noted, however, that, "[i]n the market for a product with high fixed costs," such as a brand pharmaceutical product, "evidence that prices routinely exceed marginal costs may not necessarily be evidence that prices are supracompetitive, because even competitive prices may exceed marginal cost." In re Asacol Antitrust Litig., 323 F.R.D. 451, 484 (D. Mass. 2017), rev'd on other grounds 907 F.3d 42 (1st Cir. 2018). As Judge Casper explained in Solodyn, treating such evidence as sufficient to establish market power would result in finding that all pharmaceutical companies exercised monopoly power. See 2018 WL 563144, at *11. In that case, the generic manufacturers' gross margins ranged from 40% to 62%. The fact that the generics' gross margins were so high suggested that the brand manufacturer's high margins alone were insufficient to demonstrate supracompetitive pricing. Id. Judge Casper therefore found that there was a material dispute of fact regarding the evidence of supracompetitive pricing, given that the difference in marginal profit between the brand and generic may have been explained by characteristics specific to the pharmaceutical industry. Id.

Plaintiffs further argue that the price of Intuniv, both brand and generic, fell sharply once generic options became available. [FWK 303 at 9–10]. In November 2014, the last month before generic options became available, Intuniv's average wholesale price was $9.39 per pill.

[Id. at 9]. After generics entered the market, the average price, for either generic or brand Intuniv, was $1.41 per pill. [Id. at 9]. Factoring in rebates for brand Intuniv prior to generic entry, which accounted for roughly [redacted] of the brand price, the price still declined from roughly [redacted] per pill to [redacted] per pill. [Id. at 9–10].

Defendants' argument in opposition is two-fold. First, they argue that the falling price of Intuniv, both brand and generic, upon generic entry is insufficient direct evidence of market power. [FWK 312 at 54]. As Judge Casper has previously explained, "evidence of restricted output is used to determine whether high margins and prices are indicative of monopoly power." Solodyn, 2018 WL 563144, at *12. Second, Defendants argue that because Plaintiffs' expert ignores the actual price that customers paid for Intuniv, a price-decline analysis is insufficient. [FWK 358-1 at 10]. Through programs such as coupons and rebates, Shire was able to keep patients' effective out-of-pocket costs the same for both brand and generic Intuniv. [Id.].

The Court finds that there is a dispute of material fact regarding Intuniv's alleged supracompetitive pricing and gross margins. Although Plaintiffs have compellingly argued that Shire's margins provide sufficient evidence of market power, the weight of such testimony is undercut by the fact that, for reasons specific to incentives provided to brand manufacturers in the pharmaceutical industry, evidence of supracompetitive pricing may be, on its own, insufficient to demonstrate market power.

b. Shire's Alleged Restricted Output

Even if Plaintiffs had provided sufficient evidence of supracompetitive prices for purposes of summary judgment, such evidence is, on its own, insufficient. Direct evidence of market power requires both "showing actual competitive prices *and* restricted output." Coastal Fuels, 79 F.3d at 196 (emphasis added); see also Sterling Merch. Inc. v. Nestle, S.A., 724 F. Supp. 2d 245, 268 (D.P.R. 2010) ("Market power exists only when competitors lack capacity to

increase short run output, allowing for the monopolist to unilaterally restrict output in order to charge higher prices."). "Absent any evidence of restricted output, . . . evidence of high margins is insufficient direct evidence as a matter of law to demonstrate market power." Solodyn, 2018 WL 563144, at *12. Plaintiffs argue that they have direct evidence of restricted output before generic Intuniv became available, thereby demonstrating Shire's market power. [FWK 303 at 10].

First, the Court reiterates that evidence of supracompetitive pricing alone is insufficient to establish restricted output. Solodyn, 2018 WL 563144, at *12 ("Plaintiffs argue that the evidence of supracompetitive prices 'necessarily means that [Defendant's] conduct reduced output,' relying upon 'the law of supply and demand,' but evidence of restricted output is used to determine whether high margins and prices are indicative of monopoly power." (quoting plaintiffs' brief)).

In the years preceding generic Intuniv's entry to the market in December 2014, Shire's output remained relatively constant. [FWK 374-1 ¶¶ 101–02]. After generics were available, output increased steadily over twelve quarters, until output was 32.4% above the quarterly average before generic Intuniv entered the market. [Id.]. Defendants argue that Plaintiffs have not established that the increased output was caused by generics entering the market, as opposed to some other explanation, such as increases in ADHD diagnoses. [FWK 358-1 at 9]. Dr. Gregory Bell, Defendants' expert, identifies other potential explanations for the increase in output, such as the decreased promotion of Strattera, another ADHD treatment medication, as well as a decline in clonidine IR usage. [Id.; FWK 325-43 ¶ 37]. Plaintiffs respond that the decline in Strattera promotion began a year after Shire increased output for Intuniv and that there

was in fact no decline in clonidine IR usage, such that Intuniv could have captured that market. [FWK 373-1 at 6–7].

The Court finds that there is a dispute of fact as to whether Shire restricted its output of Intuniv. Although Plaintiffs have provided evidence that the availability of Intuniv increased after generics entered the market, Shire has put forth sufficient evidence concerning other possible causes for the increase in Intuniv availability to create a dispute of fact and thereby preclude summary judgment.

c. Shire's Alleged Reverse Payment

Finally, Plaintiffs claim that they have provided evidence of a reverse payment of approximately $30 million. [FWK 303 at 11]. Defendants argue in opposition that the undisputed evidence shows that Shire did not pay Actavis to delay generic competition. [FWK 312 at 27]. Under the Supreme Court's holding in Actavis, if a brand company agrees to sacrifice some of its profits and transfer them to a generic as part of a settlement agreement, the Court may infer that the unexplained payment was given in exchange for the generic delaying entry. See, e.g., Edlin et al., supra, at 589 ("Justice Breyer's opinion in Actavis established the Actavis Inference. Put simply, in the pharmaceutical context: if Brand pays more than its prospective litigation costs to Generic, a firm threatening entry with a generic version of the same drug; and if Generic agrees not to offer that version for some period of time; then a fact-finder may properly infer that such a large and unexplained payment was made to delay generic entry, and hence is anticompetitive." (internal quotation marks and citation omitted)). In the presence of such a large payment, "anticompetitive effect and market power can be inferred from the large payment itself, if the payment was larger than the patent holder's anticipated litigation costs." Id. at 590. Defendants argue that the Actavis Inference is inapplicable in this case because Shire did not sacrifice any profits and, therefore, there was no large, unexplained

payment. Though the Actavis Inference is most easily applied to cash settlements, courts have extended the principle to cases involving non-cash settlements. For example, a reverse settlement may include an agreement by the brand company not to launch an AG, if the brand company "give[s] up the valuable right to capture profits" from an AG launch and "transfers [those profits] to the settling generic." King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp., 791 F.3d 388, 405 (3d Cir. 2015); see also In re Loestrin 24 Fe Antitrust Litig. (Loestrin III), 261 F. Supp. 3d 307, 333 (D.R.I. 2017) (finding that a no-AG Agreement constituted a reverse payment because it transferred payments to the settling generic company that the brand company would have otherwise received by distributing an AG); Edlin et al., supra, at 598 ("[N]o-AG provisions are even more worrisome from an antitrust perspective than are reverse payments made in cash. No-AG provisions should be treated as a form of reverse payment, the magnitude of which must be estimated on a case-by-case basis. The Actavis Inference that a large and unexplained reverse payment is anticompetitive should apply to sufficiently valuable no-AG provisions.").

Alternatively, if, at the time of the settlement, the settling parties also enter into a business arrangement that is below fair market value, the Court may infer that said business deal functioned as a reverse payment. Loestrin III, 261 F. Supp. 3d at 338 (finding that the "sum total" of business agreements "constituted a large and unjustified payment"). A settling party might also forgive debts or liability from the other party, for example, settling a different case between the parties. In re Lipitor Antitrust Litig., 868 F.3d 231, 253 (3d Cir. 2017) (holding that plaintiffs had adequately pled a reverse payment agreement based on brand's settlement of case with generic company in exchange for a settlement in a different case). Royalty payments are, in themselves, insufficient to constitute a reverse payment. See In re Actos End Payor Antitrust

Litig., No. 13–cv–09244, 2015 WL 5610752, at *15 (S.D.N.Y. Sept. 22, 2015), vacated in part on other grounds, 848 F.3d 89 (2d Cir. 2017).

Defendants make two arguments in support of their contention that they did not make a payment to Actavis. First, they argue that, because according to Plaintiffs' expert it was more profitable for Shire to collect royalties than to launch its own AG, Shire did not sacrifice anything in this case. [FWK 312 at 31]. The question, however, is not whether, after engaging in a potentially unlawful agreement, Shire made more money than it would have otherwise and thus did not sacrifice profits. Rather, the question is whether, by declining to launch its own AG, Shire sacrificed profits that it otherwise would have had by not launching its own generic or by not taking a larger percentage of royalties.

Second, Defendants argue that, by securing its right to launch its own AG, Shire did not sacrifice any profits. [FWK 312 at 32]. Plaintiff maintain, however, that Shire had no intention of launching, and did not have the capacity to launch, an AG on its own. Therefore, even assuming that Shire had retained its right to launch an AG, there would remain a dispute of fact concerning whether Shire sacrificed potential profits by limiting its ability to launch an AG with a third party.

The Court therefore finds that there is a dispute of material fact as to whether Shire made a large payment to Actavis. Additionally, even if there were not such a dispute, though the Actavis Inference may be sufficient for purposes of surviving a motion to dismiss, the burden on Plaintiffs is higher at summary judgment. Solodyn, 2018 WL 563144, at *5 ("That is, an allegation of a 'large, unjustified' reverse payment is sufficient for a plaintiff to state a claim under Section 1, but is not necessarily sufficient to demonstrate market power at the summary judgment stage, particularly where, as here, the [d]efendants dispute that the reverse payments at

issue were both large and unjustified." (quoting Actavis, 570 U.S. at 158)). Therefore, even in the absence of a dispute of material fact concerning whether Shire made a large reverse payment to Actavis, Plaintiffs would need to put forth more evidence than the payment itself in order for summary judgment in their favor as to market power to be appropriate.

2. Indirect Evidence of Market Power

Indirect evidence of a company's market power includes evidence "that the defendant has a dominant share in a well-defined relevant market and that there are significant barriers to entry in that market and that existing competitors lack capacity to increase their output in the short run." Coastal Fuels, 79 F.3d at 197; see Cramer and Berger, supra, at 85 ("[C]ourts have traditionally permitted claimants to meet their burden of establishing maintenance or creation of monopoly power by first defining a 'relevant product market' or 'relevant market' and subsequently showing that the defendant firm possesses a dominant share of that market."). The relevant market refers to both the relevant geographic market and the relevant product market. Here, the parties do not dispute that the relevant geographic market is the United States and its territories. [FWK 140 ¶ 182]; see generally [FWK 303, 312, 355, 358, 373, 375].

With regard to the relevant product market, the "market is established by examining both the substitutes that a consumer might employ and 'the extent to which consumers will change their consumption of one product in response to a price change in another, i.e., the cross-elasticity of demand.'" Flovac, 817 F.3d at 854 (quoting Eastman Kodak, 504 U.S. at 469). "The definition of the relevant market is ordinarily a question of fact, and the plaintiff bears the burden of adducing enough evidence to permit a reasonable factfinder to define the relevant market." Id. at 853.

a. Cross-Price Elasticity

Products are in the same relevant product market only "where there is cross-elasticity of demand, i.e. if customers would switch to alternatives in response to a price increase in the alleged monopolist's product." United Food & Commer. Workers Local 1776 v. Teikoku Pharma USA (Lidoderm), 296 F. Supp. 3d 1142, 1167 (N.D. Cal. 2017); see also Loestrin III, 261 F. Supp. 3d at 327 ("Products are not reasonably interchangeable merely because they are similar forms or functions, but rather '[s]uch limits are drawn according to the cross-elasticity of demand for the product in question—the extent to which purchasers will accept substitute products in instances of price fluctuation and other changes.'" (quoting Nexium III, 968 F. Supp. 2d at 387–88)). Cross-price elasticity "measures 'the substitutability of products' by gauging the 'responsiveness of the demand for one product [X] to changes in the price of a different [Y].'" Solodyn, 2018 WL 563144, at *6 (alterations in original) (quoting Mylan Pharms., 838 F.3d at 437).

Plaintiffs argue that Intuniv had cross-price elasticity only with generic Intuniv, such that it was not competing with other non-stimulant ADHD treatments. [FWK 303 at 6, 13]. Plaintiffs' expert, Dr. Christopher Baum, uses a data set of prices and the Almost Ideal Demand System to create models to calculate the cross-price elasticity of demand. [Id. at 13]. He concludes that "there is no statistically significant nor economically meaningful evidence of positive cross-price elasticity of demand with respect to Intuniv's price for potential therapeutic alternatives to Intuniv." [FWK 374-1 ¶ 134; FWK 380-1 ¶ 17]. Defendants claim that Plaintiffs' expert's testimony concerning cross-price elasticity is unreliable because it does not compare the actual out-of-pocket costs paid by patients and third-party payors. [FWK 312 at 56]. Defendants' expert, Dr. Bell, argues that although the Court should consider cross-price elasticity when products compete on the basis of price, "[t]o the extent that competition is

primarily driven by other factors one should consider 'the reasonable interchangeability of use.'" [FWK 374-1 ¶ 107 n.237].

The Northern District of California has considered and rejected a similar argument. In Lidoderm, the defendants argued that an expert's testimony as to cross-price elasticity was inappropriate because he "relied on wholesale acquisition cost . . . as opposed to net price (after rebates or other incentives)." 296 F. Supp. 3d at 1175. The court found that the plaintiffs had presented sufficient evidence that "during the relevant time there was no significant cross-elasticity of demand between [the brand drug] and any other product other than [the] generic." Id. at 1176. The court concluded that the relevant market was therefore limited to the brand drug and its generic options. Id.

Courts in this district have interpreted Lidoderm narrowly, however, and have found that the court's holding in that case was in part based on the fact that the defendants sought an unnecessarily broad definition of the relevant market, "including a wide array of pain medications, including opioids, anticonvulsants, antidepressants, muscle relaxers, nonsteroidal anti-inflammatory drugs and topical anesthetic creams and gels," and that the defendants in that case did not put forth any evidence of cross-price elasticity. Solodyn, 2018 WL 563144, at *9; see also Lidoderm, 296 F. Supp. 3d at 1171 ("Defendants point to no cases arising in the pharmaceutical context where courts (or juries) have defined the relevant market as broadly as they seek here. Indeed, in the pharmaceutical context courts have limited the market to similar classes of drugs or even more narrowly, down to the brand product itself in the absence of cross-elasticity evidence."). In this case, the Defendants do not seek such a broad definition of the relevant market, but limit the market to non-stimulant ADHD treatments, and have also put

forth the exact evidence found sufficient in Solodyn, evidence of rebates and coupons and other promotional activity. Solodyn, 2018 WL 563144, at *8–9.

Defendants next argue that Plaintiffs' use of the Hypothetical Monopolist Test is inappropriate outside of the merger context. [FWK 312 at 57]. As the Court has previously noted in its memorandum and order on the motions to exclude, [FWK 419 at 15], the Eastern District of Pennsylvania has recently found that the Hypothetical Monopolist Test is inappropriate in a non-merger pharmaceutical antitrust case, due to the unique pricing practices in the pharmaceutical industry including rebates and discounts. See AbbVie, Inc., 329 F. Supp. 3d at 129. "[A]pplication of the [test] would result in a market limited to a brand-name drug and its AB-rated generic in almost every instance." Id. at 130. Other courts have not yet endorsed that court's reasoning and, in the First Circuit, it remains true that "the hypothetical monopolist test is the 'touchstone of market definition,' even in contexts outside of horizonal mergers" Asacol, 323 F.R.D. at 471; see also Coastal Fuels, 79 F.3d at 198 ("The touchstone of market definition is whether a hypothetical monopolist could raise prices.").

The ABA Model Jury Instructions have also adopted the Hypothetical Monopolist Test in determining whether two products are in the same relevant product market. "To determine whether products are reasonable substitutes for each other, you must consider whether a small but significant and non-transitory increase in the price of one product would result in enough customers switching from that product to another product such that the price increase would not be profitable." Model Jury Instructions in Civil Antitrust Cases A-108 n.2 (Am. Bar Ass'n 2016). See also Solodyn, 2018 WL 563144, at *6 ("When products are close economic substitutes, a small change in [the] price of one product will cause consumers to shift and sales to respond accordingly, meaning the cross-elasticity of demand will be high.").

The Court finds that there is a dispute of material fact as to whether brand Intuniv had cross-price elasticity only with itself and generic versions. As in Solodyn, Defendants have put forth evidence of Shire's use of rebates and coupons, which undercuts Plaintiffs' arguments for cross-price elasticity, and also provide evidence that Shire was competing with other non-stimulant ADHD treatments, which the Court considers in greater detail below. See Solodyn 2018 WL 563144, at *10 (denying summary judgment as to both parties on the issue of market power after plaintiffs put forth evidence of cross-price elasticity, which defendants argued was insufficient in the pharmaceutical context, and defendants put forth evidence of promotional activity, such as rebates and coupons); see also Mylan Pharms., 838 F.3d at 437 (noting that the defendants' evidence "demonstrated that [d]efendants responded to the market's reaction to their prices with sales promotions in an effort to increase their ability to compete with other tetracyclines"). The issue of cross-price elasticity must therefore go to a jury.

b. Therapeutic Interchangeability

Defendants argue that Intuniv is therapeutically interchangeable with other non-stimulant ADHD treatments, such that the relevant product market should not be limited to brand and generic Intuniv.[11] Therapeutic interchangeability is, on its own, insufficient to establish the relevant market. "[E]ven where products are essentially identical, that alone is insufficient to require their inclusion in the relevant market." Lidoderm, 296 F. Supp. 3d at 1171; see also Solodyn, 2018 WL 563144, at *8 ("Even in the pharmaceutical market, . . . cross-elasticity must

[11] The FDA classifies products as therapeutically interchangeable when they are both pharmaceutically equivalent, meaning that they contain the same amount of the same active ingredients in the same dosage form, and bioequivalent, meaning that they are absorbed at the same rate and to the same extent. See Ctr. for Drug Evaluation & Research, Food & Drug Admin., Approved Drug Products with Therapeutic Equivalence Evaluations, §§ 1.2, 1.7 (40th ed. 2020), available at https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

be demonstrated between products to establish a market definition that includes them."). "Products are not reasonably interchangeable merely because they share similar forms or functions, but rather '[s]uch limits are drawn according to the cross-elasticity of demand for the product in question—the extent to which purchasers will accept substitute products in instances of price fluctuation and other charges.'" Loestrin III, 261 F. Supp. 3d at 327 (quoting Nexium III, 968 F. Supp. 3d at 387–88); see also Model Jury Instructions in Civil Antitrust Cases at A-108 n.2 ("In assessing whether products are within the relevant market, the jury must consider not only whether the products are functionally similar but also whether the products are economically interchangeable. That is, there must be cross-price elasticity of demand . . . .").

Defendants argue that Shire's own record and rebate history support the conclusion that it understood that it was competing with all non-stimulant ADHD treatments. See, e.g., Solodyn, 2018 WL 563144, at *8 (considering evidence that defendant pharmaceutical companies themselves did not previously view the allegedly therapeutically interchangeable treatments as economic competitors in their own forecasts, reports, or advertising); see also Lidoderm, 296 F. Supp. 3d at 1170 (considering the fact that internal documents demonstrated that the brand treatment was marketed and promoted in competition with other drugs, besides the brand and generic versions). Defendants' expert, Dr. Bell, determined that many formularies required patients to try preferred non-stimulants before covering Intuniv and that prescribers would switch patients between Intuniv and other non-stimulant treatment based on price and formulary coverage. [FWK 358-1 at 13; FWK 325-43 ¶¶ 16–46]. Additionally, Shire offered rebates to health plans and coupons to individual patients to make the price of Intuniv comparable to that of generics and other non-stimulant treatments. [FWK 358-1 at 14; FWK 380-1 ¶¶ 18–19].

Dr. Bell claims to arrive at a representation of therapeutic interchangeability by reviewing "[c]linical guidelines, formulary decisions, and physicians prescribing behavior." [FWK 301-82 ¶ 22]. In analyzing the percentage of utilization among non-stimulants, he found that, as the price for Intuniv decreased, Shire's market share of the non-stimulant market increased. [FWK No. 360-1 at 16]. For example, Dr. Bell considered formulary competition, which tracks the rebate payments made by drug manufacturers to health plans to ensure a favorable placement on the plan's formulary. Shire paid [redacted] in rebates to managed care organizations and [redacted] in rebates to Medicaid from 2010 to 2014 to obtain a favorable formulary position as compared to other products used to treat ADHD. [Id. at 12]. He also reviewed patient-level price competition, such as Shire's offering coupons to patients to reduce out-of-pocket costs. [Id. at 13]. As of November 2014, prior to Actavis' entry, Shire had paid $48.3 million in coupons for patients to purchase Intuniv. [Id.].

Finally, Dr. Bell looked to Shire's own promotional materials which revealed that Shire targeted physicians who prescribed non-stimulants to treat ADHD, but were not prescribing Intuniv. [Id. at 14]. Internal documents further evidence that Shire sought to increase its share of the "Non-Stim Adjunct Market," or the market where non-stimulant ADHD medications are prescribed in addition to a stimulant. [Id. at 15]. Such expert evidence has been found to be credible in other cases. In AbbVie, for example, the court found that the relevant market should not be limited to the brand and generic versions of a drug, but should also include all testosterone replacement therapy treatments based on price competition within that treatment market, including things such as rebates, promotional expenses, and internal documents that show that the company viewed itself as competing with the other treatments. 329 F. Supp. 3d at 131–32.

Plaintiffs' expert, Dr. Thomas Fernandez, stated his belief that Intuniv was not "therapeutically interchangeable" with other non-stimulant ADHD medications. [FWK 301-3 ¶¶ 33–36]. In arriving at this conclusion, Fernandez viewed "therapeutic interchangeability" as follows: "if you had five drugs that were therapeutically interchangeable, you could close your eyes, pick one at random, and you would be fine doing it that way." [FWK 325-183 at 65]. According to Dr. Fernandez, Intuniv is not, for example, interchangeable with Strattera because Intuniv does not include a warning that it could cause active suicidal ideation and Intuniv does not have risks of liver or cardiovascular issues. [FWK 301-3 ¶ 34]. Additionally, Fernandez does not believe that Intuniv is interchangeable with Kapvay because Intuniv is less sedating and does not cause low blood pressure. [Id.].

Some courts have found that evidence of rebates and internal comparisons with other treatments is insufficient to establish interchangeability for purposes of market power. See, e.g., Lidoderm, 296 F. Supp. 3d at 1174 ("Defendants cite evidence that [the brand company] consistently tracked its sales/prescriptions of [the brand drug] in comparison with therapeutically similar products . . . . But defendants do not show that the availability of those other products *forced* [the brand company] to limit its [brand drug] price or otherwise constrained [its] pricing."). In this case, however, Defendants have provided evidence that many formularies required patients to try other non-stimulant ADHD treatments before covering Intuniv, which suggests that competing with other non-stimulant treatments did force Shire to engage in such rebate and coupon programs. [FWK 374-1 ¶¶ 134–46]; see also Solodyn, 2018 WL 563144, at *9 (distinguishing that case from Lidoderm because the defendants "provide[d] a basis, which amount[ed] to a disputed issue of fact, regarding [p]laintiffs' purported showing that

cross-elasticity of demand . . . demonstrate[d] that the relevant market [wa]s limited to [the brand] and its generic equivalents").

Therefore, although therapeutic interchangeability is, on its own, insufficient to establish market power, the Court finds that Defendants have adduced evidence that Shire seemed to compete with other non-stimulant ADHD treatments by offering coupons and rebates which undercuts Plaintiffs' cross-price elasticity analysis and leaves a disputed material fact that precludes summary judgment on the issue of therapeutic interchangeability.

3. Disputes of Material Fact Make It Inappropriate for the Court to Determine Whether, as a Matter of Law, the Relevant Market Is Limited to Brand and Generic Intuniv

Because there are reasonable disputes of material fact concerning the direct and indirect evidence regarding market power in this case, the issue of market power must be resolved by a jury. The motion for summary judgment based on the contention that Shire had market power in a market limited to brand and generic Intuniv is therefore DENIED.

B. Whether Defendants Agreed That Shire Would Not Launch an Intuniv Authorized Generic

In a reverse payment case, the Court applies the rule of reason. First, Plaintiffs must "'prove anticompetitive effects,' by demonstrating 'a payment for delay, or, in other words, payment to prevent the risk of competition.'" Loestrin III, 261 F. Supp. 3d at 329 (quoting King Drug Co., 791 F.3d at 412). In assessing whether the payment had anticompetitive effects, the Court must consider "its size, its scale and relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." Id. (quoting Actavis, 570 U.S. at 159). Once Plaintiffs have demonstrated such a payment, the burden shifts to Defendants "to show that [the] challenged payment was justified by some procompetitive objective." Id. (quoting Nexium II, 42 F. Supp.

3d at 262–63). If Defendants make such a showing, the burden then shifts once again to Plaintiffs to establish that the deal's anticompetitive effects outweigh its procompetitive benefits. Id. Defendants argue that Plaintiffs have failed to provide sufficient evidence at step one, the alleged payment.

First, Defendants argue that the Agreement itself explicitly allowed Shire to launch an AG. [FWK 312 at 13]. Second, Defendants argue that Actavis consistently sought a no-AG agreement, but Shire refused. [Id. at 13–14]. Third, Defendants argue that it would have been reasonable, and in fact in Shire's best interest, to launch an AG. [Id. at 14].

Under Section 1 of the Sherman Act, plaintiffs must prove that the defendants engaged in an unlawful agreement, express or implied, that restrained trade. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 553 (2007); White v. R.M. Packer Co., Inc., 635 F.3d 571, 575 (1st Cir. 2011). "Independent decisions by individual firms [that] . . . 'lead to the same anticompetitive result as an actual agreement among market actors,' . . . are not prohibited by federal antitrust laws." Nexium II, 42 F. Supp. 3d at 250 (quoting White, 635 F.3d at 575).

"[C]onduct as consistent with permissible competition as with illegal conspiracy does not, standing alone, support an inference of antitrust conspiracy." Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587–88 (1986); see also In re Chocolate Confectionary Antitrust Litig., 801 F.3d 383, 396 (3d Cir. 2015) ("[E]ven when armed with a plausible economic theory, a plaintiff relying on ambiguous evidence alone cannot raise a reasonable inference of a conspiracy sufficient to survive summary judgment."); Euromodas, Inc. v. Zanella, Ltd., 368 F.3d 11, 19 (1st Cir. 2004) ("In Sherman Act cases . . . the permissible inferences that can be drawn from ambiguous evidence are quite limited. If the evidence shows conduct that is as consistent with lawful competition as it is with an illicit conspiracy, it cannot be said to

support an inference of concerted action."). The Second Circuit, however, has further clarified that "broader inferences are permitted, and the 'tends to exclude' standard is more easily satisfied, when the conspiracy is economically sensible for the alleged conspirators to undertake and 'the challenged activities could not reasonably be perceived as procompetitive.'" In re Publ'n Paper Antitrust Litig., 690 F.3d 51, 63 (2d Cir. 2012) (quoting In re Flat Glass Antitrust Litig., 385 F.3d 350, 358 (3d Cir. 2004)). Therefore, "[i]n order to survive summary judgment, plaintiff[] must produce direct or circumstantial evidence that is not only consistent with conspiracy, but 'tends to exclude the possibility of independent action.'" White, 635 F.3d at 577 (quoting Monsanto Co. v. Spray-Rite Service Corp., 465 U.S. 752, 764 (1984)).

1. Direct Evidence

a. The Agreement Itself

Defendants first argue that the Agreement itself plainly preserved Shire's ability to launch an AG, such that there was no agreement to the effect that Shire would not compete with Actavis in the generic market during its 180-day period of market exclusivity. [FWK 355-2 at 15]. It is undisputed that the Agreement contains a no third-party AG provision that prevents Shire from distributing an AG through a third party. [FWK 380-1 ¶ 81]. Section 2.3 of the Agreement preserves Shire's right to launch an AG by providing that "Shire explicitly retains the right itself, or through an Affiliate, to Market at any time an AG Product." [Id. § 2.3].

Plaintiffs argue, however, that other terms in the Agreement demonstrate that Defendants understood that Shire would not in fact launch an AG. Section 5.1.1 specifies that Shire's royalties would decline if other generics entered the market. [FWK 380-1 ¶ 81 § 5.1.1 ("For the avoidance of doubt, this royalty obligation is terminated on the date of the First Commercial Sale by a Third Party *or Shire or its Affiliates* of a Generic Equivalent Product *or an AG Product* . . . ." (emphasis added)]. Section 8.8.2 further provides that, if Actavis sought a preliminary

injunction to stop Shire from permitting another party to launch an AG, Shire could not assert a "no irreparable injury" defense. [FWK 380-1 ¶ 155; Id. ¶ 81 § 8.8.2 ("Shire acknowledges that in the event that Shire . . . [m]arkets an AG Product without providing notice as required under Section 2.3 ('Failure to Notify'), the damages to [Actavis] and its business . . . may be difficult to calculate and the adequacy of monetary damages calculated at Law would be uncertain. Accordingly, Shire agrees that in any action by [Actavis] seeking injunctive or other equitable relief in connection with any . . . Failure to Notify, [Actavis] shall be entitled to specific enforcement of the terms and conditions set forth in this License Agreement, and *shall be entitled to immediate relief to prevent an Early Shire AG Launch.* Shire shall not assert or plead the availability of an adequate remedy at Law as a defense in obtaining any such remedy." (emphasis added))].

The Court has previously explained that Shire's "explicit reservation . . . does not on its own preclude the existence of an *implicit* no-AG agreement . . . ." Picone v. Shire, No. 16-cv-12396, 2017 WL 4873506, at *9 (D. Mass. Oct. 20, 2017) (emphasis added). A contract that purports to prohibit an unlawful agreement is insufficient to establish the lack of such an agreement, however, if the plaintiff puts forth sufficient evidence to suggest that the contract was merely used as a cover to mask an unlawful intent. In United States v. Imperial Chemical Industries, the Southern District of New York found that the parties had entered into a contract to "camouflage" the parties' unlawful and anticompetitive intent. 100 F. Supp. 504, 544 (S.D.N.Y. 1951). Similarly, in United States v. McDonough, the First Circuit found that a lobbyist had used a standard agreement with a legislator's law firm to mask payment for political favors. 727 F.3d 143, 154 (1st Cir. 2013). Therefore, though the contract itself suggested that the parties had not entered into an unlawful agreement, the court found that it was simply an attempt to hide the

parties' true intent. The Court therefore finds that the explicit terms of the Agreement do not alone establish whether Defendants agreed between themselves that Shire would not launch an AG.

b. Course of Dealing

Defendants next argue that, throughout the negotiations leading to the Agreement, Shire consistently guarded its ability to launch an AG. Actavis first approached Shire about a no-AG agreement in September 2012, immediately after the bench trial in the Delaware district court. [FWK 312 at 18; FWK 380-1 ¶ 50]. More specifically, Actavis proposed an October 2013 launch date, that it pay no royalty to Shire, and that Shire provide a no-AG agreement. [FWK 312 at 18; FWK 380-1 ¶ 50]. Shire countered with a January 2016 launch date, a 15% royalty that declined as more generics entered the market, and Shire retaining its ability to launch an AG. [FWK 312 at 18; FWK 380-1 ¶ 51]. Over the next few months, Shire and Actavis negotiated those core terms (entry date, royalty, and whether Shire could launch an AG) until agreeing to: an entry date of December 2014; a royalty rate of 25% for the first 180 days of Actavis' sales, which would be voided if Shire entered the market with an AG; and that Shire would be permitted to distribute an AG itself but not through a third party. [FWK 312 at 18–19; FWK 380-1 ¶ 66–77]. Actavis was particularly interested in Shire providing a no-AG agreement and requested such an agreement on five separate occasions during negotiations. As a compromise, Shire agreed not to use a third party to launch an AG, but insisted that it retain the right to distribute its own generic.

Plaintiffs respond that the course of dealings nonetheless makes it clear that Shire did not actually intend to launch an AG, but instead was only seeking to insulate itself from a lawsuit such as this. They point to Tatjana May, Shire's then-General Counsel, expressly saying, on Shire's behalf, that "for Shire not to be able to retain its right to launch an AG would be an

unacceptable risk to the company." [FWK 380-1 ¶ 66]. When questioned further during her deposition about why it would be a "risk to the company," May explained that she "told [Actavis] that the risk to [Shire] of not retaining [its] right to launch an authorized generic would be an unacceptable risk to [Shire]." [Id.] When asked what "risk" she was referring to, May said, "[t]hat we would get sued." [Id.; FWK 301-14 at 55]. Therefore, Shire insisting that it reserve its right to launch an AG does not mean that Shire intended to launch such a generic or to even consider it.

The Court therefore finds that there is a dispute of material fact as to what Actavis' and Shire's settlement negotiations show about whether the parties secretly entered into a no-AG agreement, such that no reasonable jury could find that the parties unlawfully agreed that Shire would not launch a generic during Actavis' 180-day period of market exclusivity. Although the evidence suggests that Shire insisted that it retain its right to launch an AG, Plaintiffs have provided sufficient evidence to create a material dispute of fact as to why Shire insisted that the Agreement include that language.

2. Indirect Evidence

In addition to the Agreement itself and Defendants' negotiations, Defendants point to three forms of indirect evidence that they believe establish that they did not agree that Shire would not launch an AG.

First, Defendants point to the fact that, in 2014, after it had already entered into the Agreement with Actavis, Shire had a meeting for which it created forecasts as to expected returns, to discuss whether it could launch its own AG without the use of a third party. [FWK 312 at 22; FWK 380-1 ¶¶ 121–29]. Plaintiffs argue that Shire's exploration of an AG was simply a pretext to ensure a defense to litigation such as this. Their expert, Dr. Thomas McGuire, questions "whether the documents were created to generate a false record of Shire

'considering' an AG launch." [FWK 355-2 at 19; FWK 380-1 ¶ 121; FWK 349-21 ¶ 24 ("I note that as a matter of sound practice in the area of applied microeconomics, it is important for the economist to evaluate whether particular sources of data or information are reliable. I note that the July 2014 Shire exercise appears to have been created under questionable circumstances. As described in my April 2019 Report, Shire was aware of the potential antitrust issues of the Shire-Actavis agreement. Dr. Cockburn's blind use of the purported July 2014 exercise fails to investigate whether the documents were created to generate a false record of Shire 'considering' an AG launch should the company be accused of engaging in anticompetitive conduct.")]. According to Plaintiffs, Shire's decision to explore the launch of an AG on its own originated with its antitrust attorneys. [FWK 380-1 ¶ 121]. In fact, according to Plaintiffs, after they alleged that Shire had never distributed an AG without the help of a generic company, Shire modified an existing contract with a generic company regarding a different AG to make it appear that Shire was distributing that AG on its own. [FWK 355-2 at 17]. In addition, Plaintiffs state that after Defendants entered into the Agreement, Shire stopped forecasting AG profits and analyzed only its potential royalties under the Agreement, [FWK 355-2 at 15], and also dismantled its manufacturing operations for an AG, [id. at 16]. Similarly, Actavis stopped including an AG in its forecasts. [Id. at 15].

Second, Defendants argue that there is no evidence that the royalty provision acted as an enforcement mechanism for an implicit no-AG agreement. [FWK 312 at 24]. The royalty negotiations occurred before the discussions concerning Shire's right to launch a generic. [Id. at 25]. Further, there is no evidence that those negotiating the Agreement ever communicated that the royalty provision could act as an enforcement tool to dissuade Shire from launching a generic. [Id.]. Even if Shire had attempted to determine a break-even point, or whether the

royalties could be as profitable as launching its own AG, Shire's own experts have determined that it would always have been more profitable for Shire to launch a generic rather than collecting royalties from Actavis' sales. [Id.]. According to Plaintiffs, there is evidence that both companies understood that Shire would make more from the royalty agreement than from distributing an AG. [FWK 355-2 at 20]. Plaintiffs' expert, Dr. McGuire, believes that Shire expected to make $27.6 million if it launched an AG and $31.6 million if it did not launch a generic and instead received the royalties from Actavis' sales. [FWK 380-1 ¶ 97 (explaining Dr. McGuire's opinion that the "25% rate . . . is above the threshold royalty rate that makes it unprofitable for Shire to enter with an AG, indicating that the royalty split's purpose is to enforce an implicit no-AG agreement.")]. Plaintiffs therefore argue that Shire and Actavis spent months debating the exact royalty provision in order to reach a number that would effectively incentivize Shire to stay out of the generic market. [FWK 355-2 at 20–21].

Third, Defendants argue that the indirect evidence suggests that Shire had the means to carry out the launch of an AG. [FWK 312 at 26]. Though Shire, under the terms of the agreement, could not have contracted with a third-party distributor, it still could have launched an AG on its own. [FWK 380-1 ¶ 81 § 2.3 ("Shire explicitly retains the right itself, or through an Affiliate, to Market at any time an AG Product.")]. Defendants' expert, Harsha Murthy, opines that a reasonable company in Shire's position could have launched an AG on its own without needing distribution through a third-party generic drug distributor. [FWK 301-72 ¶ 59]. Plaintiffs respond that Shire has never distributed an AG itself or through an affiliate, and has only ever distributed through generic sellers. [FWK 355-2 at 16].

More generally, Plaintiffs argue that brand companies do not market their own AG products themselves. [FWK 355-2 at 16]. According to Plaintiffs' expert, Michael Johnson,

brand companies do not distribute their own AGs, unless they have previous generic experience, which Shire did not. [FWK 380-1 ¶ 82]. Johnson discusses a report from the Federal Trade Commission (the "FTC") which found that, out of 119 AG launches from 2001 to 2008, only one was distributed by a brand drug company without generic marketing. [Id.]. Additionally, out of the 529 AG launches since 2009 that Johnson analyzed, only two were distributed by a brand company without generic expertise. [Id.]. Plaintiffs' expert Dr. McGuire relies on a 2019 report from the FTC, which found that certain settlements included "a commitment from the brand manufacturer not to use a third party to distribute an authorized generic for a period of time, such as during first-filer exclusivity." [Id. ¶ 170]. In the report relied on by Plaintiffs' expert, the FTC concluded that a brand company's promise "not to use a third party to distribute an AG" has "the same effect as an explicit no-AG commitment . . . if the brand company does not market generics." [Id. (quoting from FTC report)]. Although, in its report, the FTC noted that "[a]nalysis of whether there is compensation requires inquiry into specific marketplace circumstances, which [was] beyond the scope of th[e] summary report," "[t]his type of commitment could have the same effect as an explicit no-AG commitment . . . if the brand company does not market generics in the United States." Food Drug Cosm. L. Rep. ¶ 400, 152, Report Highlights Reverse Payment Agreements Reduction in Fiscal Year 2016, 2019 WL 2723599 (May 23, 2019).

Further, according to Plaintiffs, Shire issued a press release about the Agreement, explaining that the Agreement required that Actavis would pay Shire "during the 180 day period of Actavis' exclusivity," which implies that Shire had no intention of launching its own AG. [FWK 355-2 at 15]. Actavis issued a similar press release with the headline "180 Days of

Exclusivity," [id. at 15–16], and communicated internally that it had a launch that was "exclusive without an AG for 180 days," [id. at 16].

The Court finds that there is a material dispute of fact as to whether the indirect evidence establishes that Shire and Actavis did not enter into an implicit no-AG agreement. If Shire and Actavis agreed that Shire would not launch an AG so that Actavis would be free from generic competition during its period of market exclusivity, then such an agreement would violate the Sherman Act. Whether or not the parties entered into a no-AG agreement, however, when the Agreement itself explicitly reserves Shire's right to launch an AG is a question of fact that should be left to a jury and is an inappropriate determination at the summary judgment stage.

Considering both the direct and indirect evidence, the Court finds that Plaintiffs have put forth enough evidence to create a dispute of material fact as to whether Defendants agreed that Shire would not launch an AG, despite the fact that the Agreement contained an explicit provision retaining Shire's right to launch an AG on its own. Summary judgment is therefore DENIED as to whether the Defendants agreed that Shire would not launch an AG.

C. Whether Plaintiffs Have Demonstrated Causation by Relying on Launching at Risk

Plaintiffs argue that, but for the Agreement, Actavis would have (1) won a favorable verdict in the patent litigation both in the Delaware district court and before the Federal Circuit, (2) launched at risk, or (3) entered into an agreement with Shire to enter the market earlier in the absence of a reverse payment. [FWK 355-2 at 33, 35]. "[A]n antitrust plaintiff must prove that he or she suffered damages from an antitrust violation and that there is a causal connection between the illegal practice and the injury." Nexium II, 42 F. Supp. at 267; see also Sullivan v. Nat'l Football League, 34 F.3d 1091, 1103 (1st Cir. 1994) (noting that, in addition to demonstrating an antitrust violation, plaintiffs must show that the antitrust violation was a

"material cause" of their injury). The antitrust violation may still cause their injury "even if there are additional independent causes of the injury." Nexium II, 42 F. Supp. 3d at 267 (internal citations and quotation marks omitted). "'Once a plaintiff presents evidence that he suffered the sort of injury that would be the expected consequence of the defendant's wrongful conduct,' the burden shifts to the defendant to rebut this causal inference." In re Neurontin Mktg. and Sales Practices Litig., 712 F.3d 21, 45 (1st Cir. 2013) (quoting BCS Servs., Inc. v. Heartwood 88, LLC, 637 F.3d 750, 757 (7th Cir. 2011)). "[C]ausation is generally a question best left for the jury." Loestrin II, 433 F. Supp. 3d at 323.

If the antitrust claim is built upon the possibility that the settling generic company would have otherwise launched at-risk, then the existence of a valid and infringed patent is an independent bar that precludes harm because the generic could not, in fact, have entered the market. Nexium I, 842 F.3d at 63. Plaintiffs must therefore establish that Shire's "patents would have been declared invalid or that an at-risk launch would not have infringed the patent . . . . [W]ithout such evidence, the 'patent serve[s] as an independent regulatory bar to [a generic's] launch.'" Id.

1. Whether Shire and Actavis Were Ready and Able to Launch a Generic Intuniv Product

Plaintiffs seek summary judgment on Actavis' readiness and ability to distribute generic Intuniv by November 15, 2012, and Shire's readiness and ability to distribute an AG on that same day. [FWK 295].[12] Plaintiffs argue that "[i]t is undisputed that, but for the alleged anticompetitive conduct, both Actavis and Shire would have been ready and able to distribute their generic Intuniv products by November 15, 2012," even if neither party would have been willing to launch a generic. [FWK 302 at 5].

[12] Though the DPPs filed the motion, [FWK 295], the IPPs subsequently joined, [Picone 237].

Plaintiffs in a reverse-payment case may prove causation by showing that, were it not for the defendants' anticompetitive agreement, a cheaper, generic option would have been available sooner than it was. Asacol, 323 F.R.D. at 488. The Court must therefore determine whether a reasonable jury could find that Actavis "would have overcome regulatory and other hurdles" to enter the market sooner if it had not entered into the Agreement with Shire. Nexium II, 42 F. Supp. 3d at 269. The inquiry "requires looking at two separate questions:" whether the companies had the "will" to enter the market and whether there was a "way" for them to do so. Id. at 270; see also In re Wellbutrin XL Antitrust Litig., 133 F. Supp. 3d 734, 767–68 (E.D. Pa. 2015) (separately analyzing whether a manufacturer could launch and whether it would have done so). Though Plaintiffs concede that Defendants may dispute whether they were "willing" to launch generic Intuniv, they argue that there is no dispute that both Actavis and Shire were ready and able to launch a generic option. [FWK 302 at 9].

a. Whether Actavis Was Ready and Able to Launch Generic Intuniv

Plaintiffs argue that, even if Actavis was unwilling to launch at risk, it was ready and able to do so. As the Court has previously explained, launching at-risk means launching a generic product with the risk of losing a patent infringement case brought by the brand company. Nexium I, 842 F.3d at 40–41. To succeed on their at-risk launch theory of causation, Plaintiffs must show that Actavis could have launched at-risk without infringing any lawful Shire patent. "Without such a showing, the patent[s] held by [Shire] would serve as 'an independent regulatory bar' to [Actavis'] at-risk launch." Solodyn, 2018 WL 563144, at *13 (quoting Nexium I, 842 F.3d at 63). Plaintiffs must provide "some evidence" that the Shire patents at issue were invalid or that the Actavis generic launch would not have infringed on those patents. Nexium I, 842 F.3d at 63.

Beginning on August 6, 2012, Actavis began manufacturing, testing, and packaging twelve test batches of generic Intuniv. [FWK 302 at 7]. Two weeks after Actavis received FDA approval of its ANDA, the twelve batches were "launch ready." [Id.]. Plaintiffs' expert, Donald Allen, testifies that "Actavis had in place the planning and decision-making processes" to enable it to ensure that "the 9 commercial batches it expected to need for launch would [be] planned and executed on time." [FWK 374-1 ¶ 51]. Allen concludes that a reasonable company in Actavis' position would have been launch ready by November 15, 2012. [FWK 302 at 13].

Though "Defendants do not dispute that Actavis could have satisfied the regulatory and manufacturing conditions for generic Intuniv by November 15, 2012," they argue that Actavis would not have obtained board approval to launch by that date. [FWK 359-1 at 6]. According to Defendants, Actavis had been told by its parent company that it was not to launch generic Intuniv while the Delaware district court proceedings were ongoing. [FWK 359-1 at 8; FWK 374-1 ¶¶ 122–25]. Defendants argue that the Delaware district court might have ruled in Shire's favor, another court might have granted an injunction to stop Actavis from distributing generic Intuniv, or the FDA might have rescinded tentative approval. [FWK 359-1 at 8–9]. Plaintiffs maintain that because "none of these circumstances *actually* occurred[,] this Court may safely ignore Actavis's 'conclusory allegations, improbable inferences,' and 'rank speculation.'" [FWK 302 at 10 (quoting Ahern v. Shinseki, 629 F.3d 49, 54 (1st Cir. 2010))].

Such considerations, however, go to whether Actavis would have been willing to launch at risk, which the Court considers in greater detail below, not whether Actavis was ready and able. Other courts have found that a company's review of possible litigation results is properly considered as part of the analysis as to whether the company was "willing" to launch at risk. See, e.g., Lidoderm, 74 F. Supp. 3d at 1074. ("Defendants dispute plaintiffs' characterization of

the Watson earnings calls, and argue that Watson was not willing to launch at-risk because they expressed concern about the ongoing Citizen Petition.").

Therefore, Defendants have not put forth any evidence to establish that Actavis was not "ready" or "able" to launch a generic version of Intuniv by November 15, 2012, but instead merely argue that it was not "willing" to do so, because it would have risked damages in the ongoing patent litigation with Shire. Therefore, the motion for summary judgment as to the Defendants' readiness and ability to launch a generic Intuniv, [FWK 295], is GRANTED as to Actavis. The question remains, however, whether Actavis would have been willing to launch an a generic Intuniv, given the litigation risks.

b. Whether Shire Was Ready and Able to Launch an Authorized Generic

Plaintiffs argue that Shire has admitted that it "had no impediments that would have prevented Shire from commercially marketing an AG Intuniv product [by the third week of] November 2012." [FWK 302 at 13–14 (quoting FWK 374-1 ¶ 64)]. Defendants counter that Shire had made no decision as to whether to launch an AG by November 15, 2012. [FWK 359-1 at 11–12]. This argument, however, goes to whether the company was *willing* to launch an AG, not whether it had the capacity to do so.

In September 2012, Shire entered into an agreement with Anchen Pharmaceuticals, a generic drug manufacturer, which provided that if Actavis launched generic Intuniv at-risk and Shire decided to allow an AG, Shire would provide said generic to Anchen to market during Actavis' 180-day period of exclusivity. [FWK 302 at 8]. Shire agreed that it would provide one lot of each strength of Intuniv by November 15, 2012, or within thirty days of Actavis' potential at-risk launch. [Id.].

Because Defendants have not put forth any evidence to counter Plaintiffs' demonstration that Shire was ready and able to launch an AG, and instead argue only that it was not willing to do so, the motion for summary judgment as to readiness and ability, [FWK 295], is GRANTED as to Shire.

2. Whether a Jury Can Consider Claim Construction

Defendants argue that Plaintiffs may not premise their theory of causation on Actavis' failure to launch at risk, because it would require a jury finding that Actavis was likely to succeed on the merits in the underlying patent litigation, and on a potential appeal before the Federal Circuit. Defendants assert that, at the time of the Agreement, three different district courts had issued orders that construed the patent claims differently. In particular, courts construed "element 1(c)" differently. Though Judge Andrews was the first federal judge to construe the claim, two other judges later rejected his construction. [FWK 312 at 40; FWK 380-1 ¶¶ 42–43]. On appeal, the Federal Circuit would therefore have had to address the different claim constructions under *de novo* review. [FWK 312 at 41]. "Whether a generic manufacturer is willing to risk treble damages from a patent infringement suit by selling a generic drug at risk is generally a factual issue." Lidoderm, 74 F. Supp. at 1074.

Defendants argue that asking a jury to determine whether the Federal Circuit would have upheld Judge Andrews' order on claim construction would be impermissible, as the Supreme Court has consistently held that claim construction is not a jury issue. [FWK 312 at 42]. "[T]he construction of a patent, including terms of art within its claim, is exclusively with the province of the court." Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996). Markman, however, concerns patent cases, not antitrust cases such as this. [FWK 355-2 at 43].

The Supreme Court has explained that

> it is normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham). An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness.

Actavis, 570 U.S. at 157. Some courts, however, have limited the implications of the Supreme Court's guidance in Actavis and found that the Supreme Court was referring only to actions brought by the FTC. See, e.g., In re Wellbutrin XL Antitrust Litig., 133 F. Supp. 3d at 764. The Third Circuit, for example, has found that, though the "size of a reverse payment may have some relevance in determining how confident a litigant is in the strength of its case," the reverse payment is, itself, insufficient to establish causation. In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 169 (3d Cir. 2017).

In Nexium II, Judge Young granted summary judgment on the plaintiffs' at-risk launch causation theory because he found that the at-risk causation theory was too speculative. 42 F. Supp. at 290 ("It is too speculative as a matter of law to assume that [the generic company] would have prevailed in its actions *and* seen those rulings affirmed by the Federal Circuit. Moreover, the [p]laintiffs are unable to offer a reasonable timeline for when these lawsuits could have been won, making it difficult to conclude that this scenario would have yielded a market entry date before May 2014." (citations omitted)); see also id. at 290 n.13 (noting that the Federal Circuit "reverses claim construction decisions as much as 44 percent of the time"). Similarly, the Northern District of Georgia recently granted summary judgment on plaintiffs' causation theory based on patent merits because "a jury would have to determine how the judge [in the underlying litigation] would have decided various legal issues, including claim

construction and summary judgment." In re Androgel Antitrust Litig. (No. II), 09-md-02084, 2018 WL 2984873, at *13 (N.D. Ga. June 14, 2018).

Plaintiffs argue that they need not demonstrate that Actavis would have won the underlying patent litigation, but must provide only "some evidence of the patent's invalidity or noninfringement" to "pursue an at-risk launch theory." [FWK 355-2 at 36 (quoting Nexium I, 842 F.3d at 63)]. The First Circuit has held that a plaintiff in a reverse settlement case must put forth "some evidence" that the brand company's patents would have been declared invalid or that an at-risk launch would not have infringed on the brand company's patents. Nexium I, 842 F.3d at 63. Otherwise, the brand company's patents act as "an independent regulatory bar to [a generic's] launch." Id. (quoting In re Wellbutrin XL Antitrust Litig., 133 F. Supp. 3d at 764); see also id. ("The district court thus did not err by requiring some evidence of the patents' invalidity or noninfringement before allowing the plaintiffs to pursue an at-risk launch theory."). "The clear import of Nexium and Wellbutrin is that a plaintiff must offer some evidence of non-infringement or patent invalidity in order to proceed on an at-risk launch theory of causation." Apotex, Inc. v. Cephalon, Inc., 255 F. Supp. 3d 604, 614 (E.D. Pa. 2017).[13] Therefore, Plaintiffs must put forth "some evidence of the patents' invalidity or noninfringement before allowing the plaintiffs to pursue an at-risk launch theory." Nexium I, 842 F.3d at 63.

In both Solodyn, 2018 WL 563144, at *13, and Lidoderm, 296 F. Supp. 3d at 1155, the courts allowed the issue of whether a generic company was likely to succeed in the underlying

[13] Other courts, however, have been more lenient and have held that a plaintiff need not demonstrate that the patent would have been found invalid or that an at-risk launch would not have infringed on said patent. E.g., Lidoderm, 296 F. Supp. 3d at 1155. Those courts have found that "consideration of whether the agreement is justified as procompetitive will not turn on whether the patent would ultimately have been proved valid or invalid," because "[a]greements must be assessed as of the time they are made . . . at which point the patent's validity is unknown and unknowable." Id. (quoting In re Cipro Cases I and II, 348 P.3d 845, 870 (Cal. 2015)).

patent litigation to go to a jury, despite similar causation arguments. See Solodyn, 2018 WL 563144, at *20 ("Defendants have failed to demonstrate as a matter of law that the [] patent would serve as an independent bar to [the generic company's] at-risk launch. Although [d]efendants are correct that [p]laintiffs must provide evidence of noninfringement as part of their at-risk scenario, [p]laintiffs need only provide '*some evidence*' that their at-risk launch would have been lawful." (emphasis added)).

Therefore, the Court finds that a jury may consider whether Plaintiffs have provided sufficient evidence to establish Actavis' likelihood of success on the merits in the patent trial. This is different from determining whether Actavis would have prevailed, which would require litigating a patent case within this antitrust case. Defendants' motion for summary judgment as to whether Plaintiffs have demonstrated causation is therefore DENIED.

3. Plaintiffs Have Provided Sufficient Evidence That Actavis Would Have Succeeded at Trial and On Appeal

Defendants argue that, even if the jury can consider whether it appeared likely that Actavis would have won the underlying patent litigation, Plaintiffs have failed to provide sufficient evidence such that a reasonable jury could find that Actavis would have prevailed in the underlying patent litigation. [FWK 312 at 44]. First, Judge Andrews denied Actavis' motion for summary judgment on non-infringement, meaning that the judge believed that a reasonable jury could have found in Shire's favor. [Id. at 46]. Second, other courts, in construing the same patents, have construed the patent claims differently. These differences of opinion mean that Plaintiffs cannot establish that the Federal Circuit would have upheld Judge Andrews' claim construction. See [FWK No. 380-1 ¶ 37 (discussing Judge Andrews' construction in the instant case); id. ¶ 42 (discussing construction by the District of Colorado); id. ¶ 43 (discussing the construction by the Northern District of California)].

In this context,

> [T]he correct antitrust analysis must be based on what was reasonably known to the parties about patent validity at the time they entered into their settlement. Stated differently, the antitrust analysis of a reverse-payment settlement should be made on an ex ante basis, as of the date of the settlement itself. A subsequent finding of patent invalidity does not imply that there was an antitrust violation, regardless of the presence or size of a reverse payment. Nor does a subsequent finding of patent infringement imply there was no antitrust violation despite a large and unexplained reverse payment.

Edlin et al., supra, at 617. Thus, to prevail at trial, the Plaintiffs need not prove as a matter of law that Actavis would have succeeded in the underlying patent litigation. See, e.g., Lidoderm, 296 F. Supp. 3d at 1155–56 ("I disagree that plaintiffs need to prove *in this case* that Watson *would have* won its patent litigations. That turducken is not only unappetizing as a matter of judicial efficiency, it is not required (or even suggested) by the Actavis opinion. Instead, to put their at-risk launch theory of antitrust causation to the jury, plaintiffs must show 'some evidence' that Watson could have won at trial . . . or on appeal at the Federal Circuit."); see also Solodyn, 2018 WL 563144, at *14 (agreeing with Lidoderm and finding that "the standard requiring [p]laintiffs to produce 'some evidence' of invalidity or noninfringement does not require [p]laintiffs 'to prove that the generic defendant *would have* won, only that it *could have*'"). Rather, the Plaintiffs must provide evidence about what Shire and Actavis believed their bargaining positions to be at the time that they negotiated the Agreement. "The antitrust question has to do with whether competition was likely to have been reduced by the settlement, based on the information available to the parties at the time they settled their patent litigation. Relying instead on subsequent patent validity findings carries a heavy risk of hindsight bias." Edlin et al., supra, at 619; see also Apotex, Inc., 255 F. Supp. 3d at 611 (finding that a patent ruling which postdated the relevant settlement agreement was irrelevant under the Actavis rule of reason analysis).

The Court finds that Plaintiffs have provided sufficient evidence to survive summary judgment on the issue of whether Actavis was likely to prevail in the underlying patent litigation, such that Shire's patents were not an independent regulatory bar to Actavis launching a generic alternative. Plaintiffs' expert, John Thomas, concludes that Shire had very little chance of succeeding in its patent infringement claims against Actavis. [FWK 325-45 ¶ 73]. Although the Court has excluded Thomas' specific statistical finding as to Shire's likelihood of success, he will be permitted to testify as to Shire's general likelihood of success on the merits in an underlying patent case in reverse-payment litigation. [Picone 334]. Further, Plaintiffs' experts Drs. Mansoor Amiji and Michael Cima believe that, "as an objective, scientific matter," Shire's patents were anticipated and/or obvious in light of the prior art existing at the time of the filing. [FWK 325-177 ¶ 4; FWK 325-178 ¶ 15]. Such evidence is sufficient to create a dispute of material fact as to whether Shire was likely to succeed on the merits in the underlying patent litigation or whether, absent the Agreement, Actavis could have launched generic Intuniv sooner than the entry date permitted in the Agreement.

D. Whether Plaintiffs Can Recover for Purchases Made Before Any Alleged Anti-Competitive Agreement

Defendants next seek summary judgment on Plaintiffs' claims seeking damages for purchases they made before April 25, 2013, the date that Shire and Actavis entered into the Agreement. [FWK 312 at 47]. Plaintiffs seek damages for purchases made after November 15, 2012. [FWK 234 at 10 n.2; Picone 146 at 1]. Defendants argue that a company does not violate Section 1 of the Sherman Act by, on its own, deciding to not pursue a generic launch, because such an action depends on an agreement between the brand and the generic manufacturers. [FWK 312 at 49–50].

Plaintiffs cannot recover for injuries that were not caused "by reason of anything forbidden in the antitrust laws." 15 U.S.C. § 15(a). Plaintiffs argue that they are entitled to damages arising before Shire and Actavis entered into the Agreement in April 2013 because they have pled that Defendants engaged in an ongoing scheme to limit competition and Actavis could have launched a generic Intuniv alternative as soon as November 15, 2012. [FWK 312 at 49; FWK 355-2 at 45]. The FDA approved Actavis' ANDA on October 5, 2012, and Plaintiffs' expert projects that it would have taken Actavis six weeks from the approval date to be launch ready. [FWK 380-1 ¶ 198]. Plaintiffs claim that the evidence shows that the conspiracy began as early as November 2, 2012, when Shire emailed a draft settlement agreement that included a no third-party launch proposal. [FWK 355-2 at 46–47]. The parties then began negotiating the specific terms of the settlement agreement, which are outlined above. [Id. at 47–48].

"Defendants do not dispute" that "it is sometimes possible to infer the existence of an agreement before it is reduced to writing and signed." [FWK 375-2 at 29]. The Southern District of New York has explained that an anticompetitive agreement may begin before the allegedly conspiring parties enter into any formal agreement and may include the discussions that led to that formal agreement. See United States v. Apple Inc., 952 F. Supp. 2d 638, 703 (S.D.N.Y. 2013) ("Apple's entry into the conspiracy had to start somewhere, and the evidence is that it started at those initial meetings in New York City with the Publishers."). In that case, the court found sufficient evidence that the conspiracy started during negotiations because there were phone calls between the parties, in-person visits, and emails to solidify specific provisions. Id. at 704–05. The court explained that "while this conspiracy was complex to execute, its terms were relatively simple and required no extended discussion," and that "[t]he issue was whether Apple and the Publishers would join together to eliminate Amazon's power to set retail prices

and then to raise prices to the point that Apple would permit. The most hotly contested negotiations revolved around just how high those prices would go." Id. at 705; see also Moraine Products v. ICI Am., Inc., 538 F.2d 134, 146 (7th Cir. 1976) ("[T]here was evidence from which a jury could infer that, even prior to the formal execution of the challenged contract, there was some form of agreement the effect of which would be to limit in numbers those catering to the needs of the substantial market of customers plagued with [particular] symptoms.").

Plaintiffs have provided sufficient evidence to create a reasonable dispute of material fact as to whether, if Defendants entered into an unlawful agreement to restrain competition, that agreement began when the parties first began negotiating their settlement in November 2012 or began when the parties entered into the Agreement in April 2013. A jury could find that Defendants had entered into an unlawful agreement before April 2013 and that the purpose of the Agreement was to maximize value for Defendants and provide sufficient protection from antitrust liability. Summary judgment is therefore DENIED as to whether Plaintiffs may seek damages for purchases made before April 2013.

E. IPPs' State-Law Claims

1. Evidence That the TWi/Anchen Settlement Was Anticompetitive or Injured IPPs

When Shire settled with Actavis, it had already settled patent claims related to Intuniv against TWi and Anchen. [FWK 312 at 58]. According to the terms of that settlement, TWi and Anchen could launch a generic on July 1, 2016, and would pay royalties of [redacted]. [FWK 312 at 58; FWK 380-1 ¶ 44]. Due to a "most favored nation" provision, however, the entry date was eventually pushed up to December 1, 2014, and the royalty terms became the same as in the Agreement. [FWK 312 at 58; FWK 380-1 ¶ 44]. Additionally, the agreement included that Shire could use Anchen

to launch an AG and, in the event that the TWi/Anchen ANDA was not approved by the FDA by July 1, 2016, Shire would supply Anchen with an Intuniv AG for one year, which guaranteed that a generic Intuniv would be on the market by July 2016 at the latest. [FWK 380-1 ¶ 45].

The "IPPs agree that they no longer seek to establish that the Shire settlement with TWi/Anchen, on its own and independent of any other conduct, was anticompetitive" and contend that "[t]he [D]efendants' motion, therefore, should be denied as moot in this narrow respect." [FWK 355-2 at 59 n.287]. The IPPs argue, however, that "[s]ummary judgment must be denied to the extent the [D]efendants seek to preclude the IPPs *from referencing the TWi/Anchen settlement* as part of Shire's overarching scheme to monopolize the Intuniv market." [FWK 355-2 at 59 (emphasis added)]. This, however, is not the relief that Defendants seek in their motion for summary judgment. Therefore, Defendants' motion for summary judgment is GRANTED because the IPPs no longer seek to establish that Shire's settlement with TWi/Anchen was, itself, anticompetitive.

2. Overarching Scheme

The IPPs brought three underlying claims supporting the overarching scheme theory: first, that Shire engaged in sham patent litigation; second, that Shire entered into the previously discussed anticompetitive settlement agreement with TWi/Anchen; and, third, that Shire entered into the instant anticompetitive settlement with Actavis. [Picone 39 ¶ 79 ("The combination of a late date certain by which TWi/Anchen could enter the market with their own generic (i.e., July 1, 2016), plus the ability to sell Shire's AG product, was instrumental in Shire's overarching anticompetitive scheme. By settling with TWi/Anchen first, Shire created anticompetitive leverage over Actavis—the first filer—to settle at non-competitive terms. . . . In short, the Shire-TWi/Anchen settlement provided a crucial bargaining chip for Shire in its anticompetitive

negotiations with Actavis—namely, the threat of a third-party AG that would compete with Actavis's product.")].

The Court previously dismissed the IPPs' sham litigation claims, [Picone 92 at 14–15], and, as discussed above, the IPPs now "agree that they no longer seek to establish that the Shire settlement with TWi/Anchen, on its own and independent of any other conduct, was anticompetitive," [FWK 355-2 at 59 n.287]. Defendants argue that, because the IPPs no longer seek to prove that the Shire-TWi/Anchen agreement was anticompetitive and because the Court has already dismissed the sham litigation claim, the Agreement is, on its own, insufficient to establish an overarching scheme. [FWK 312 at 59–60]; see In re Solodyn (Minocycline Hydrochloride) Antitrust Litig. (Solodyn II), No. 14-md-02503, 2015 WL 5458570, at *13 (D. Mass. Sept. 16, 2015) ("The direct purchasers argue that an overarching scheme can be an antitrust violation even if parts of the scheme individually are not themselves unlawful. However, when 'alleged instances of misconduct are not independently anti-competitive . . . they are not cumulatively anticompetitive either.'" (quoting Eatoni Ergonomics, Inc. v. Research in Motion Corp., 486 F. App'x 186, 191 (2d Cir. 2012)).

Courts do not require that every single action in an anticompetitive scheme be, on its own, anticompetitive. Even courts citing the cases relied upon by Defendants have found that a plaintiff need only effectively plead one instance of anticompetitive behavior. "[P]laintiffs proceeding under an anticompetitive scheme theory must plead *at least one* instance of conduct that is not protected from antitrust scrutiny." Simon and Simon, PC v. Align Tech., Inc., No. 19-cv-00506, 2020 WL 1975139, at *7 (D. Del. Apr. 24, 2020) (emphasis added) (citing Eatoni Ergonomics, 486 F. App'x at 191, and Solodyn II, 2015 WL 5458570, at *12). Therefore, the cases relied upon by Defendants simply stand for the noncontroversial assertion

that, where a plaintiff has failed to demonstrate that any action was anticompetitive, there can be no overarching anticompetitive scheme. However, "a plaintiff can allege a series of actions that when taken together make out antitrust liability even though some of the individual actions, when viewed independently, are not all actionable." In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig., No. 13-md-02445, 2017 WL 3967911, at *15 (E.D. Pa. Sept. 8, 2017) (internal quotation marks and citation omitted); see also LePage's Inc. v. 3M, 324 F.3d 141, 162 (3d Cir. 2003) (explaining that, when determining antitrust liability based on an overarching scheme, "the courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation" (citing Cont'l Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 699 (1962))); Abbott Labs v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408, 428 (D. Del. 2006) ("Plaintiffs are entitled to claim that individual acts are antitrust violations, as well as claiming that those acts as a group have an anticompetitive effect even if the acts taken separately do not.").

Actavis was the first generic competitor to file an ANDA and was consequently entitled to a 180-day period of market exclusivity, after which time other generic companies, including TWi and Anchen, could have entered the market. Therefore, any attempt to control the date upon which generic alternatives could have entered the market depended on an agreement with Actavis regarding its entry date. Any agreement with TWi and Anchen was, on its own, insufficient to control generic entry. Plaintiffs argue that by settling with TWi and Anchen first, Shire was able to signal that it was prepared to launch an AG, such that Actavis would agree to a later entry date than it otherwise would have. [FWK 355-2 at 59]. Though the IPPs do not seek to prove that the TWi/Anchen settlement was, on its own, anticompetitive, they have provided sufficient evidence to create a dispute of material fact as to whether Shire and Actavis entered

into an anticompetitive agreement to delay competition with generic Intuniv. Because the conduct that Plaintiffs allege is sufficiently anticompetitive, Plaintiffs may seek to prove that Shire engaged in an ongoing and overarching scheme to limit competition. Therefore, the motion for summary judgment as to the IPPs' claim that Shire engaged in an overarching scheme to control generic competition is DENIED.

3. IPPs' Consumer Protection or Unfair and Deceptive Acts Claims

Defendants next argue that the IPPs have failed to provide evidence to support their state-law consumer protection, unfairness, or deception claims beyond the alleged violations of the Sherman Act. [FWK 312 at 60]. The Court has already found that a jury could find that Plaintiffs have successfully brought claims for violation of state law absent violations of the Sherman Act. Picone v. Shire, 2017 WL 4873506, at *14–20. Therefore, a jury could find that, though Plaintiffs failed to establish that Defendants violated the Sherman Act, they may have violated the relevant state laws. Such an argument is more appropriate on a motion for judgment as a matter of law after Plaintiffs have presented their evidence.

4. Claims Under Massachusetts Law

Counts One through Five of the IPPs' complaint allege causes of action under Massachusetts law. [Picone 39 ¶¶ 156–228]. The Court previously allowed the Massachusetts state-law claims to go forward because "the alleged anticompetitive conduct plausibly could violate Chapter 93A even if it does not constitute a Sherman Act violation." Picone v. Shire, 2017 WL 4873506, at *15. The Court noted, however, "that at summary judgment, if applicable, the IPPs should clarify the scope of the state law and Sherman Act in relation to the conduct that may be actionable under either law." Id. The IPPs have not done so. See generally [FWK 355].

Defendants claim that the IPPs have failed to allege that any of them were injured in Massachusetts. [FWK 312 at 61]. Picone, Cummisford, and Wright did not purchase Intuniv in

Massachusetts, while Richard purchased Intuniv once in Massachusetts in March 2013, before the date of the Agreement. [FWK 312 at 61]. The IPPs respond that out-of-state plaintiffs may assert claims under Chapter 93A. [FWK 355 at 61]; see, e.g., Geis v. Nestlé Waters N. Am., Inc., 321 F. Supp. 3d 230, 241 (D. Mass. 2018) (permitting a Florida plaintiff to sue under Chapter 93A and declining "to hold that Massachusetts residents are the only consumers who can bring chapter 93A actions, particularly when a consumer is harmed by a fraudulent statement that was made in Massachusetts").

Chapter 93A "expressly provides that no action may be brought under the statute unless the complained-of-conduct occurred 'primarily and substantially' within the Commonwealth." Monahan Products LLC v. Sam's East, Inc., – F. Supp. 3d —, 2020 WL 2561255, at *16 (D. Mass. May 20, 2020) (quoting Mass. Gen. Laws ch. 93A, § 11). Defendants bear the burden of proving that the relevant conduct occurred outside of Massachusetts. Id. The Court must then determine "whether the center of gravity of the circumstances that give rise to the claim is primarily and substantially within the Commonwealth." Kuwaiti Danish Comput. Co. v. Digital Equip. Corp., 781 N.E.2d 787, 799 (Mass. 2003).

Based on the briefing before the Court at this stage in the proceeding, Defendants have demonstrated that the allegedly anticompetitive actions did not take place "primarily and substantially" within Massachusetts. Although Shire's headquarters and principal place of business are now in Massachusetts, [FWK 380-1 ¶ 8], at the time of the alleged antitrust conspiracy, Shire's headquarters and business operations relative to Intuniv were all located in Pennsylvania and the Shire parties responsible for negotiating the agreement were predominantly located in Pennsylvania as well. [FWK 380-1 ¶ 8]. Shire has manufacturing facilities within the Commonwealth, [FWK 380-1 ¶ 8 n.28], but the presence of such facilities is insufficient under

93A, see Monahan Products, 2020 WL 2561255, at *17 (rejecting plaintiff's argument that it could bring an action under 93A because defendant stored products in a warehouse in Massachusetts because the relevant conduct was the advertising of said products, not where they were stored).

Finally, though Richard lived in Massachusetts until May 2012, she made only one purchase of Intuniv within the Commonwealth, in March 2013, before Shire and Actavis had entered into the Agreement. [FWK 380-1 ¶ 4]. Even if that pre-Agreement purchase were sufficient to constitute an injury, "a place of injury within Massachusetts is not a sufficient basis for finding that conduct occurred 'primarily and substantially' within the Commonwealth." Monahan Products, 2020 WL 2561255, at *17; see also New England Gen-Connect, LLC v. US Carburetion, Inc., No. 16-cv-12270, 2019 WL 1332891, at *2 (D. Mass. Mar. 25, 2019) ("'[I]f the place of injury were the only test, practically no case involving a Massachusetts plaintiff would be exempt from c. 93A status, no matter how negligible the defendants' business activity in this State. Such a result would effectively nullify the words 'primarily and substantially within the Commonwealth,' which imply some process of measuring and weighing.'" (quoting Makino, U.S.A., Inc. v. Metlife Capital Credit Corp., 518 N.E. 2d 519, 523 (Mass. App. Ct. 1988)). Summary judgment is therefore GRANTED as to the IPPs' claims under Massachusetts law.

5. Claims Under Florida Law

Counts Six through Ten of the IPPs' complaint allege causes of action under Florida law, including the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA") and the Florida Antitrust Act. [Picone 39 ¶¶ 229–98].

The Court previously dismissed the IPPs' claims under the Florida Antitrust Act. [Picone 92 at 33–34]. Considering the FDUTPA claim, because "Florida law recognizes that a FDUTPA

claim may arise from a violation of antitrust laws such as the Sherman Act and other state antitrust laws because such a violation in and of itself is an unfair method of competition," In re Processed Egg Prods. Antitrust Litig., 851 F. Supp. 2d 867, 900 (E.D. Pa. 2012), the Court allowed the FDUTPA claims to go forward to discovery.

According to Defendants, only Richard purchased generic Intuniv in Florida and did so after June 2, 2015 with a co-pay. [FWK 312 at 62]; see, e.g., Montgomery v. New Piper Aircraft, Inc., 209 F.R.D. 221, 227 (S.D. Fla. 2002) (dismissing plaintiffs' FDUTPA claims because there was no evidence that any plaintiff had "suffered any alleged injury in Florida"). The IPPs argue that Defendants "have not established Ms. Richard's residency at the time she made branded Intuniv purchases in New Hampshire and Massachusetts." [FWK 355 at 62]. Therefore, they claim, because Richard purchased Intuniv in New Hampshire and Massachusetts while she was relocating from New Hampshire to Florida, "[t]he factfinder may find that she was a legal resident of Florida at the time she made some purchases in New Hampshire or Massachusetts. Or, if the factfinder finds she was a New Hampshire resident at the time she made branded Intuniv purchases in those stores, then the laws of New Hampshire or Massachusetts may apply." [FWK 355 at 62 (internal citations omitted)].

Although "some Florida case law holds that FDUTPA should be applied only to in-state consumers," all federal courts in the Southern District of Florida to have considered the issue have "held that 'FDUTPA applies to non-Florida residents if the offending conduct took place predominantly or entirely in Florida.'" Felice v. Invicta Watch Co. of Am., Inc., No. 16-cv-62772, 2017 WL 3336715, at *3 (S.D. Fla. Aug. 4, 2017) (quoting Bank of Am., N.A. v. Zaskey, No. 9:15-cv-81325, 2016 WL 2897410, at *9 (S.D. Fla. Aug. 9, 2013)). "Federal courts in Florida generally allow out-of-state consumers to pursue a claim under FDUTPA 'if the

offending conduct took place predominantly or entirely in Florida.'" Bellwether Comm. Credit Union v. Chipotle Mexican Grill, Inc., 353 F. Supp. 3d 1070, 1092 (D. Colo. 2018) (quoting Karhu v. Vital Pharm., Inc., No. 13-cv-60768, 2013 WL 4047016, at *10 (S.D. Fla. Aug. 9, 2013)).

In this case, the IPPs have failed to put forth any evidence that Richard was injured while in Florida or that the conduct giving rise to the injury took place in Florida. See Montgomery, 209 F.R.D. at 228 ("[T]here is no record evidence that any particular putative class member purchased [the product] in Florida commerce and suffered injury in Florida commerce."); see also Florida Power & Light Co. v. Nuclear Energy Inst., Inc., No. 18-cv-80118, 2018 WL 3089341, at *4 (S.D. Fla. May 10, 2018) (dismissing a FDUTPA claim because the conduct causing the injury did not occur in Florida). Summary judgment is therefore GRANTED as to the IPPs' claims under Florida law.

V. CONCLUSION

Accordingly, Plaintiffs' motion for summary judgment as to market power, [FWK 294], is DENIED; Plaintiffs' motion for summary judgment as to whether Shire and Actavis were ready and able to launch generic Intuniv, [FWK 295], is GRANTED; and Defendants' motion for summary judgment, [FWK 327; Picone 244], is GRANTED in part and DENIED in part.

SO ORDERED.

September 21, 2020

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE